issue raised in the current action was in fact actually decided in the prior proceeding; (3) there was full and fair opportunity to litigate the issue in the prior proceeding; and (4) the issue previously litigated and decided was necessary to support a valid and final judgment on the merits. *In re PCH Assocs.*, 949 F.2d 585, 593 (2d Cir. 1991). In order to invoke collateral estoppel, the party asserting preclusion "bears the burden of showing with clarity and certainty what was determined by the prior judgment." *Clark v. Bear Stearns & Co.*, 966 F.2d 1318, 1321 (9th Cir. 1992).

1. Forest's Antitrust Liability Was at Issue in the Prior Litigation

The first element of collateral estoppel is identity of the issues. Forest argues that the theory of liability in the first litigation was different than the theory presented in the instant case, because *Namenda I* and *Namenda II* only examined Forest's *prospective* potential antitrust liability *if* Forest were permitted to cease sales of Namenda IR. Because the injunction prevented Forest from halting its sales, Forest argues, that potentially anticompetitive scenario never actually occurred.

However, the Second Circuit made clear, in its *Namenda II* decision, that Forest's anticompetitive conduct began with its February 2014 announcement, and was not, therefore, purely prospective. The Circuit explicitly held that the February 2014 announcement was "tantamount to withdrawal" of Namenda IR from the market. *Namenda II*, 787 F.3d at 648. It concluded that, "Defendants' actions *effectively withdrew* Namenda IR from the market," starting with that announcement, *id.* (emphasis added), and that "Defendants' hard switch—the combination of introducing Namenda XR into the market and effectively withdrawing Namenda IR—*forced* Alzheimer's patients who depend on memantine therapy to switch to XR," *id.* at 654 (emphasis added). This Court previously characterized the *Namenda II* opinion as concluding,

"in no uncertain terms, that the illegal hard switch began well before the date Forest intended to withdraw Namenda IR." *Namenda III*, 2016 WL 4992690, at *11.

Therefore, by the plain language of the *Namenda II* decision, Forest's antitrust liability for its actions beginning in February 2014 was at issue in the prior litigation.

2. The Prior Litigation Actually Decided the Issue of Forest's Antitrust Liability

Likewise, Forest's antitrust liability stemming from the February 2014 announcement was "actually decided" in the prior litigation, thereby satisfying the second element of collateral estoppel.

In order to establish a claim of monopolization in violation of Section 2 of the Sherman Act, a plaintiff must demonstrate that (1) "the defendant possessed monopoly power in the relevant market" and (2) the defendant willfully acquired or maintained that power through anticompetitive conduct. *Namenda II*, 787 F.3d at 651. In order to establish attempted monopolization, "the plaintiff must prove: '(1) that the defendant has engaged in predatory or anticompetitive conduct with (2) a specific intent to monopolize and (3) a dangerous probability of achieving monopoly power.'" *Id.* (quoting *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456 (1993)). "Attempted monopolization, unlike monopolization, requires a finding of specific intent." *Id.* In short, a defendant violates Section 2 "only when it acquires or maintains, or attempts to acquire or maintain, a monopoly by engaging in exclusionary conduct 'as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.'" *United States v. Microsoft Corp.*, 253 F.3d 34, 58 (D.C. Cir. 2001) (en banc) (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 571 (1966)).

a. Forest Had Monopoly Power in the Relevant Market

In *Namenda I*, Judge Sweet concluded that the relevant "geographic and product market for antitrust purposes in this case has been established as the memantine market in the United States." 2014 WL 7015198, at *35. He concluded that, prior to the upcoming entry of generics into the U.S. market, Forest was "the exclusive producer[] of all forms of memantine," meaning that Forest "[has] monopoly power." *Id.* at *36. On appeal, Forest did not dispute that it possessed monopoly power over the U.S. memantine drug market until the expiration of the '703 Patent on July 11, 2015. *Namenda II*, 787 F.3d at 651-52. Therefore, the first element of a monopolization claim – monopoly power – was actually decided in the first litigation.

b. Forest's Conduct Was Coercive and Anticompetitive

The second prong of the monopolization claim – whether Forest "willfully sought to maintain or attempted to maintain [its] monopoly in violation of [Section 2]" – is analyzed under the framework established by the D.C. Circuit in *Microsoft*, 253 F.3d 34. *Namenda II*, 787 F.3d at 652. "Under the *Microsoft* framework, once a plaintiff establishes that a monopolist's conduct is anticompetitive or exclusionary, the monopolist may proffer 'nonpretextual' procompetitive justifications for its conduct. The plaintiff may then either rebut those justifications or demonstrate that the anticompetitive harm outweighs the procompetitive benefit." *Id.* (internal citations omitted) (quoting *Microsoft*, 253 F.3d at 58-59).

A product redesign is anticompetitive or exclusionary "when it coerces consumers and impedes competition." *Id.* The leading case in this circuit examining the question of whether a product redesign is coercive or anticompetitive is *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263 (2d Cir. 1979). In *Berkey Photo*, Kodak, which held a lawful monopoly in film, introduced a new type of film – Kodacolor II – that was only compatible with its new camera, the Kodak 110. The plaintiff, Berkey Photo, a small camera manufacturer, alleged that Kodak

violated Section 2 by introducing the Kodak 110 and Kodacolor II simultaneously. The Second Circuit concluded that the launch was not anticompetitive, but noted that "the situation might be completely different if, upon the introduction of the 110 system, Kodak had ceased producing film in the 126 size, thereby compelling camera purchasers to buy a Kodak 110 camera." *Berkey Photo*, 603 F.2d at 287 n.39. In *Namenda II*, the Second Circuit relied on this dictum from *Berkey Photo* for the principle that, while "neither product withdrawal nor product improvement alone is anticompetitive . . . when a monopolist *combines* product withdrawal with some other conduct, the overall effect of which is to coerce consumers rather than persuade them on the merits, and to impede competition, its actions are anticompetitive under the Sherman Act." *Namenda II*, 787 F.3d at 653-54.

In the prior litigation, it was determined that Forest's actions, starting with the February 2014 announcement of the upcoming withdrawal of Namenda IR from the market, were both coercive and anticompetitive.

First, the Second Circuit found that, "The hard switch began on February 14, 2014 with the announcement of [Forest's] intention to withdraw Namenda IR and was suspended in September 2014" after New York instigated the first litigation. *Namenda II*, 787 F.3d at 648. "Because a manufacturer does not simply withdraw a drug at once, absent pressing safety concerns, announcing the imminent discontinuation of a drug is tantamount to withdrawal." *Id.*; *see also* Merriam-Webster's Collegiate Dictionary 1277 (11th ed. 2003) (defining "tantamount" to mean "equivalent in value, significance, or effect").

Forest's February 2014 announcement was multi-faceted. In addition to issuing a press release about the upcoming discontinuance of Namenda IR sales, Forest "published open letters to physicians and caregivers on its website announcing its plans to discontinue Namenda IR and

urging caregivers to speak with their loved ones' 'healthcare provider[s] as soon as possible to discuss switching to Namenda XR.'" *Namenda I*, 2014 WL 7015198, at *18. Judge Sweet found that, "Physicians interpreted the announcement as a warning to switch their patients from Namenda IR to Namenda XR." *Id.* Forest also included the announcement in its fiscal year 2013 10-K filing with the Securities & Exchange Commission and sent a letter to the Centers for Medicare & Medicaid Services to remove Namenda IR from its Formulary Reference File – an unusual step that would make it more likely that health insurance plans would not cover Namenda IR starting in January 2015. *Id.*

Second, the Second Circuit concluded that Forest's hard switch "crosses the line from persuasion to coercion." *Namenda II*, 787 F.3d at 654. Because Namenda IR and Namenda XR were the only non-CI forms of treatment for Alzheimer's disease approved by the FDA at the time of the hard switch, discontinuation of Namenda IR would leave only one form of memantine available – Namenda XR. *Namenda I*, 2014 WL 7015198, at *5, *14-*15. "By effectively withdrawing Namenda IR prior to generic entry, Defendants *forced* patients to switch from Namenda IR to XR—the only other memantine drug on the market." *Namenda II*, 787 F.3d at 654 (emphasis added). Absent the hard switch, patients and their doctors would have been able to freely choose between Namenda IR and Namenda XR (and, eventually generic versions of Namenda IR) based solely on the merits of those products. "By removing Namenda IR from the market prior to generic IR entry, Defendants sought to deprive consumers of that choice." *Id.* at 655.

Both Judge Sweet and the Second Circuit determined that the hard switch also impeded competition. The hard switch, Judge Sweet concluded, "limits access to Namenda IR in order to overcome what [Forest CEO Brenton] Saunders called the 'inertia' that causes most patients and

physicians to resist changing medicines, with the goal of impeding lower-cost competition and the result of driving up the average price for memantine." *Namenda I*, 2014 WL 7015198, at *25. Generic drug competition would be impeded because, by its nature, such competition relies almost exclusively upon "Price competition at the pharmacy, facilitated by state generic substitution laws." *Id.* at *8. Because most generic substitution laws (including New York's) would prevent a pharmacist from automatically substituting a prescription for Namenda XR with a generic version of Namenda IR (without first consulting the patient's physician), Judge Sweet concluded that "generics are unlikely to be able to make substantial sales." *Id.* at *26; *see also id.* *27. Even in the approximately twenty states that do not rely on the FDA's Orange Book to determine therapeutic equivalence, the Second Circuit determined that "pharmacists will not be permitted to substitute generic IR for XR" because of their different dosage and absorption rates. *Namenda II*, 787 F.3d at 657. Because "competition through state drug substitution laws is the *only* cost-efficient means of competing available to generic manufacturers," *id.* at 655-56 (emphasis added), other methods of generating sales, like advertising, are not feasible for generic drug manufacturers.

Both Judge Sweet and the Second Circuit concluded that the result of the hard switch would be that a "significantly higher" number of patients would convert from Namenda IR to Namenda XR than if Forest had not attempted to pull Namenda IR from the market. *Namenda I*, 2014 WL 7015198, at *28; *id.* at *39 (hard switch would result in "inflation of [Namenda] XR's share of the memantine market"); *see also Namenda II*, 787 F.3d at 655 (holding that Forest's hard switch "has the effect of significantly reducing usage of rivals' products" (quoting *Microsoft*, 253 F.3d at 65)). Forest's own internal projections estimated that, using only soft-switch tactics, [redacted] of Namenda IR patients would voluntarily switch to Namenda XR.

Namenda I, Unredacted Op. at 80. Under a hard-switch strategy, that percentage [redacted]. *Id.* Judge Sweet determined that generic competition would only be able to capture [redacted] of the memantine market, while Forest would continue to control [redacted] if the hard switch were allowed to continue. *Id.* at 109-111. Forest estimated that the hard switch would result in more than [redacted] in additional sales of Namenda XR as compared to the soft switch. *Id.* at 80-81.

Importantly, Judge Sweet found that Forest's hard-switch tactics had *already* resulted in more customers converting from Namenda IR to Namenda XR than Forest had estimated would convert voluntarily. At the time the preliminary injunction was entered, "about 50% of existing patients [had] converted from Namenda IR to Namenda XR in anticipation of the lack of availability of Namenda IR." *Namenda I*, 2014 WL 7015198, at *29. This is significantly more than the [redacted] that Forest had estimated would convert if only soft-switch tactics were employed.

Ultimately, if the hard switch continued, it "would likely have anticompetitive and exclusionary effects on competition in the memantine market, creating a 'dangerous probability' that [Forest] would maintain [its] monopoly power after generics enter[ed] the market." *Namenda II*, 787 F.3d at 655 (quoting *Spectrum Sports*, 506 U.S. at 456). Judge Sweet noted that, in the past, market share of above 70% is usually considered strong evidence of monopoly power, while in some cases monopoly power has been found in cases where the monopolist controlled less than 50% of the relevant market. *Namenda I*, 2014 WL 7015198, at *36-*37. Here, Forest's own projections that it would continue to control more than [redacted] of the memantine market if the hard switch was allowed to continue falls squarely in the category of "strong evidence of monopoly power."

c. Forest's Procompetitive Justifications Were Rejected as Pretextual

Both Judge Sweet and the Second Circuit determined that "All of [Forest's] procompetitive justifications for withdrawing [Namenda] IR are pretextual." *Namenda II*, 787 F.3d at 658. This conclusion was based, in part, on statements made by one of Forest's own corporate officers, Brenton Saunders, who stated on an earnings call that the purpose of the hard switch was to impede generic competition. *Namenda I*, 2014 WL 7015198, at *40. Judge Sweet accordingly rejected Forest's later-in-time justification that halting sales of Namenda IR would allow the company to more efficiently "focus" on Namenda XR, which he characterized as "not as specific, or as persuasive, as [Saunders'] earlier representations to shareholders." *Id.*

Furthermore, "by contending at the hearing that a preliminary injunction against the forced switch would require significant changes to [Forest's] operations as a result of the potential loss of [redacted] in sales," Judge Sweet determined that Forest "essentially conceded that it is this expectation of [redacted] increased sales of Namenda XR that is driving [its] business decision to engage in the forced switch." *Namenda I*, Unredacted Op. at 121. "No other non-pretex[t]ual pro-competitive purpose has been established, either at the hearing or by any contemporary Forest analysis." *Id.*

d. Any Procompetitive Benefits Were Outweighed by Anticompetitive Harms

Even though Forest had failed to demonstrate the existence of any nonpretextual procompetitive justifications for the hard switch – meaning that New York had no burden to show that those justifications were outweighed by anticompetitive harms – both Judge Sweet and the Second Circuit expounded on the damage the hard switch would inflict if allowed to continue.

In *Namenda I*, Judge Sweet noted that any cost savings that could possibly result from the hard switch's "distribution efficiencies" (the only procompetitive justification that Forest attempted to quantify) would be "dwarfed" by the loss of revenue from Namenda IR sales within the first six months. 2014 WL 7015198, at *41. Furthermore, those same cost savings would also be outweighed "by the considerable anticompetitive harm: both to patients, who will pay [redacted] in higher co-payments or have to switch medications twice, and to third party payors, who will pay more than [redacted]." *Namenda I*, Unredacted Op. at 122.

In *Namenda II*, the Circuit noted that Forest's willingness to forsake short-term profits from sales of Namenda IR to achieve an anticompetitive end was "indicative of anticompetitive behavior," rather than evidence of the opposite. 787 F.3d at 659. The Circuit also flatly rejected Forest's argument that "antitrust scrutiny of the pharmaceutical industry will meaningfully deter innovation," stating that Forest "presented no evidence" to support such a claim. *Id.* "To the contrary . . . immunizing product hopping from antitrust scrutiny may deter significant innovation by encouraging manufacturers to focus on switching the market to trivial or minor product reformulations rather than investing in the research and development necessary to develop riskier, but medically significant innovations." *Id.*

"In sum," the Second Circuit concluded, "the combination of withdrawing a successful drug from the market and introducing a reformulated version of that drug, which has the dual effect of forcing patients to switch to the new version and impeding generic competition, without a legitimate business justification, violates § 2 of the Sherman Act." *Namenda II*, 787 F.3d at 659. Because the Circuit also concluded that Forest "effectively withdrew" Namenda IR from the market starting in February 2014, *id.* at 648, the prior litigation conclusively determined that Forest had violated Section 2 of the Sherman Act.

3. Forest Had a Full and Fair Opportunity to Litigate the Issue of Its Antitrust Liability in the Prior Litigation

Forest had ample opportunity to litigate its antitrust liability in the first litigation, and does not argue otherwise in the face of Plaintiffs' motion.

Judge Sweet conducted a five-day hearing on New York's request for an injunction, during which the court received 1,416 exhibits (835 of which were from Forest) and heard live or written testimony from twenty-four witnesses. *Namenda I*, 2014 WL 7015198, at *3-*4. In a meticulous 135-page decision granting the injunction, Judge Sweet made 167 findings of fact and dozens of conclusions of law regarding New York's antitrust claims, including New York's monopolization and attempted monopolization claims under Section 2 of the Sherman Act. Forest was able to seek near-immediate review of Judge Sweet's decision by a panel of the Second Circuit, which unanimously rejected all of Forest's arguments regarding the monopolization and attempted monopolization claims. Forest petitioned for rehearing of the *Namenda II* decision and for rehearing *en banc*, both of which were denied.

4. Forest's Antitrust Liability Was Necessary to a Valid and Final Judgment on the Merits

The final questions in the collateral estoppel analysis are (1) whether the decision in *Namenda II* resulted in a final judgment on the merits and (2) whether issue of Forest's antitrust liability was necessary to that decision. After a careful review of the record, the Court is convinced that the answer to both questions is "Yes."

a. The Prior Litigation Resulted in a Valid and Final Judgment on the Merits

Ordinarily, a decision granting a preliminary injunction is *not* considered "a final judicial decision based on the actual merits of the controversy" entitled to collateral estoppel effect. *Univ. of Texas v. Camenisch*, 451 U.S. 390, 395-96 (1981). A plaintiff seeking a preliminary injunction

need only "establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). A plaintiff "need not show that success is an absolute certainty." *Abdul Wali v. Coughlin*, 754 F.2d 1015, 1025 (2d Cir. 1985). As such, "findings of fact and conclusions of law made in a preliminary injunction proceeding do not preclude reexamination of the merits at a subsequent trial." *Irish Lesbian & Gay Org. v. Giuliani*, 143 F.3d 638, 644 (2d Cir. 1998).

Entry of a permanent injunction, by contrast, *is* a final judgment on the merits. *Webb v. GAF Corp.*, 78 F.3d 53, 56 (2d Cir. 1996); *see also Plummer v. Am. Inst. of Certified Pub. Accountants*, 97 F.3d 220, 229 (7th Cir. 1996). Likewise, in certain circumstances, a preliminary injunction decision may be "rendered 'practically' final," *Don King Prods., Inc. v. Douglas*, 742 F. Supp. 741, 754 (S.D.N.Y.), *on reargument*, 742 F. Supp. 786 (S.D.N.Y. 1990), depending on factors such as "the nature of the decision (i.e., that it was not avowedly tentative), the adequacy of the hearing, and the opportunity for review." *Lummus Co. v. Commonwealth Oil Ref. Co.*, 297 F.2d 80, 89 (2d Cir. 1961).

All three of the *Lummus* factors – nature of the decision, adequacy of the hearing, and opportunity for review – were present here, making the injunction final for collateral estoppel purposes.

Here, Judge Sweet entered an injunction only after conducting an extensive hearing in which twenty-four witnesses testified and Forest was permitted to submit more than 800 exhibits into evidence. *Namenda I*, 2014 WL 7015198, at *3-*4. He concluded that New York had established "sufficiently serious questions going to the merits of its claims to make them fair

ground for litigation, plus a balance of the hardships tipping decidedly in [its] favor." *Id.* at *33.[5] The injunction required Forest to "continue to make Namenda IR (immediate-release) tablets available on the same terms and conditions applicable since July 21, 2013 (the date Namenda XR entered the market)" and to "inform healthcare providers, pharmacists, patients, caregivers, and health plans of this injunction (and provide a copy of the injunction or other means to easily view the injunction) and the continued availability of Namenda IR in the same or substantially similar manner in which [it] informed them of [its] plan to discontinue Namenda IR in February 2014." Order, *Namenda I*, 2014 WL 7015198 (No. 14 Civ. 07473), Dkt. No. 84 at 1-2.

After Judge Sweet entered the injunction, Forest was able to seek immediate review of that decision at the Second Circuit. The Second Circuit not only affirmed the decision in *Namenda I*, but did so under a far more stringent standard than Judge Sweet had applied. The Circuit concluded that, because the injunction barred removal of Namenda IR from the market until after the entry of generic competition, it "provide[d] the movant with substantially all the relief sought and that relief cannot be undone even if the defendant prevails at a trial on the merits." *Namenda II*, 787 F.3d at 650. That meant the injunction, although nominally preliminary, "in effect," operated the same way "as if the injunction had been permanent." *Id.* at 651 (quoting *Eng v. Smith*, 849 F.2d 80, 82 (2d Cir. 1988)). Therefore, "a trial on the merits

[5] Judge Sweet applied the standard for a preliminary injunction articulated in *Oneida Nation of N.Y. v. Cuomo*, 645 F.3d 154, 164 (2d Cir. 2011). This standard appears at odds with the decision in *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008), in which the Supreme Court said: "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." The *Oneida Nation* standard is less demanding than *Winter*'s, since it does not require a showing of likelihood of success on the merits. However, in *Namenda II*, the Second Circuit applied a higher standard than in *Winter*, in view of the mandatory and permanent nature of the "preliminary" injunction. *See infra* at 30-31.

[would be] largely or partly meaningless." *Id.* (quoting *Tom Doherty Assocs., Inc. v. Saban Entm't, Inc.*, 60 F.3d 27, 35 (2d Cir. 1995)). This meant that New York had to demonstrate "a 'clear' or 'substantial' likelihood of success on the merits" for the injunction to remain in place – a much more demanding standard than applied by Judge Sweet, *Namenda II*, 787 F.3d at 650, and a more demanding standard than the Supreme Court articulated for preliminary injunctions in *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). That more demanding standard was met, the Circuit concluded, because New York demonstrated "a substantial likelihood of success on the merits of its monopolization and attempted monopolization claims under § 2 of the Sherman Act." *Namenda II*, 787 F.3d at 651.

Significantly, no trial on the merits was ever held in the prior litigation. By its terms, the injunction expired on August 10, 2015, thirty days after generic competition entered the memantine market on July 11, 2015. Order, *Namenda I*, 2014 WL 7015198 (No. 14 Civ. 07473), Dkt. No. 84 at 2. After the expiration of the injunction, the parties stipulated to dismissal of the entire action, including Forest's pending petition for certiorari before the U.S. Supreme Court. *See* Stipulation of Voluntary Dismissal, *Namenda I*, 2014 WL 7015198 (No. 14 Civ. 07473), Dkt. No. 96.

In its petition for certiorari, Forest described the Second Circuit's *Namenda II* decision as a final decision on the merits. While acknowledging that, "The propriety of a preliminary injunction is usually distinct from the final merits," Forest argued that, in this case, "the two issues merged." Petition for a Writ of Certiorari at 32-33, *Allergan PLC v. New York*, 136 S.Ct. 581 (2015) (No. 15-587), 2015 WL 6774554. Forest further maintained that, "While nominally addressing the propriety of the district court's preliminary injunction, the [Second Circuit] left no doubt about the merits under section 2 of the Sherman Act." *Id.* at 8. Because "the Second

Circuit reached the merits of [New York's] section 2 claim," *id.* at 32, Forest asserted that New York "cannot seek any further relief under federal law," *id.* at 33.

By Forest's own admission, the Second Circuit decided the merits of New York's antitrust claims in the first action. Forest was afforded ample opportunity to litigate those claims before Judge Sweet, and was able to have those claims reviewed on appeal. By acknowledging to the Supreme Court that New York could not seek "any further relief under federal law" for its claims, Forest admitted that New York had won on the merits. All of the *Lummus* factors – including Forest's own characterization of the *Namenda II* decision as final rather than tentative – support the conclusion that the first litigation constituted a final decision on the merits of New York's antitrust claims. *Lummus*, 297 F.2d at 89.

b. Forest's Antitrust Liability Was Necessary to that Decision

Finally, in order for collateral estoppel to apply, the issue decided in the prior litigation must have been "necessary" to the final judgment. Forest argues that, because the prior litigation only prevented Forest from halting sales of Namenda IR, any comments from *Namenda I* or *Namenda II* about Forest's antitrust liability arising from the announcement of that upcoming withdrawal were purely dicta.

Forest is mistaken. The issue of Forest's antitrust liability was necessary to the decision in the first litigation because Judge Sweet's injunction did more than require Forest to continue making Namenda IR available to doctors and patients. It required Forest to affirmatively undo the effects of its February 2014 announcement of the upcoming withdrawal by "inform[ing] healthcare providers, pharmacists, patients, caregivers, and health plans of this injunction . . . and the continued availability of Namenda IR in the same or substantially similar manner in which [it] informed them of [its] plan to discontinue Namenda IR in February 2014." Order, *Namenda I*, 2014 WL 7015198 (No. 14 Civ. 07473), Dkt. No. 84 at 1-2.

If the first litigation had only dealt with Forest's prospective antitrust liability, such affirmative steps would have been unnecessary. Imposing this requirement was an acknowledgment that Forest had *already* caused anticompetitive injury to the memantine market that had to be rectified. Therefore, in order to affirm the terms of Judge Sweet's injunction, it was "necessary" for the Second Circuit to first determine that Forest (1) possessed monopoly power over the memantine market; (2) had engaged in conduct that was both coercive and anticompetitive; and (3) lacked any non-pretextual procompetitive justifications for its coercive and anticompetitive conduct.

B. Although Forest Is Collaterally Estopped from Relitigating Questions About Its Illegal Conduct, Plaintiffs Are Not Entitled to Partial Summary Judgment on Count One

Because of all of the elements of collateral estoppel are met, Forest is precluded from re-litigating the questions of (1) whether it possessed monopoly power over the U.S. memantine market up until the entry of generic competition; (2) whether its February 2014 announcement of the upcoming discontinuation of Namenda IR was coercive and anticompetitive; and (3) whether Forest had any non-pretextual procompetitive justification for its illegal conduct. Plaintiffs' motion for collateral estoppel on these issues of fact is GRANTED. They will be presented to the jury as already decided.

However, in order for a plaintiff to establish liability on a Sherman Act monopolization claim, it must also prove that the defendant's illegal conduct resulted in antitrust injury to the plaintiff. *See Irvin Indus., Inc. v. Goodyear Aerospace Corp.*, 974 F.2d 241, 244 (2d Cir. 1992) (quoting *U.S. Football League v. NFL*, 842 F.2d 1335, 1377 (2d Cir. 1988)). In order to meet this burden, the plaintiff need only show that the illegal conduct "was a substantial or materially contributing factor" to its injuries. *Litton Sys., Inc. v. Am. Tel. & Tel. Co.*, 700 F.2d 785, 823 n.49 (2d Cir. 1983).

Forest argues that, because questions of causation and injury to Plaintiffs were not adjudicated in the prior litigation – a fact that Plaintiffs do not dispute – the Court cannot grant partial summary judgment of liability in Plaintiffs' favor. In support, Forest points to two Section 2 cases, *Howard Hess Dental Labs. Inc. v. Dentsply Int'l, Inc.*, 516 F. Supp. 2d 324 (D. Del. 2007), *aff'd*, 602 F.3d 237 (3d Cir. 2010), and *In re Microsoft Corp. Antitrust Litig.*, 232 F. Supp. 2d 534 (D. Md. 2002), *rev'd*, 355 F.3d 322 (4th Cir. 2004), in which courts declined to grant partial summary judgment to plaintiffs on the ground of collateral estoppel because the plaintiffs' injuries were not decided in the prior antitrust litigation.

In *Howard Hess*, the plaintiffs sought partial summary judgment on their antitrust claims solely on the ground of collateral estoppel, and asked the court to "infer" the existence of an antitrust injury based on a prior decision that had not made a finding of injury to the plaintiffs. *Howard Hess Dental Labs. Inc.*, 516 F. Supp. 2d at 334. The court declined to grant that motion, but did note that the findings about the defendant's monopolization from the prior litigation "Certainly . . . are to be given preclusive effect." *Id.* The district court in *Microsoft* likewise denied the plaintiffs' motions for partial summary judgment solely on the ground that the previous litigation did not address their injuries, but did give preclusive effect to hundreds of findings of fact from the prior litigation regarding the defendant's monopolization efforts. *In re Microsoft Corp. Antitrust Litig.*, 232 F. Supp. 2d at 538.

Forest is correct that a necessary aspect of Plaintiffs' Section 2 claim is proof of an antitrust injury to Plaintiffs caused by Forest's conduct, and that outstanding questions of material fact remain regarding that element of Plaintiffs' claim. Therefore, Plaintiffs' motion for partial summary judgment of liability on Count One is DENIED.

II. Plaintiffs' Motion for Partial Summary Judgment on Count Five Is Denied; Defendants' Cross-Motion for Partial Summary Judgment Dismissing Count Five Is Also Denied

In Count Five of their amended complaint, Plaintiffs assert that Defendants violated Section 1 of the Sherman Act by entering into license agreements with the seven Generic Competitors that unlawfully precluded the entry of generic competition until three months after the expiration of the '703 Patent's term. These agreements, Plaintiffs argue, were a *per se* restraint of trade because they prevented the Generic Competitors from entering the memantine market until "3 calendar months prior to the expiration of the '703 Patent, including any extensions and/or pediatric exclusivity." (*E.g.*, Pls.' Count Five 56.1 ¶ 25 n.27 (Amneal settlement agreement).) This meant that, once Forest obtained six months of pediatric exclusivity, the Generic Competitors were unable to enter the market until July 11, 2015 – three months after the '703 Patent expired.

Agreements are deemed *per se* unlawful only when they have a "predictable and pernicious anticompetitive effect." *State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997). The problem with Plaintiffs' argument is that the settlement agreements permitted the Generic Competitors to enter the market *earlier* than they could have if Defendants had prevailed in their patent infringement litigation – a generally *procompetitive* result. Plaintiffs' characterization of the agreements as *per se* anticompetitive restraints relies on the assumption that Defendants would have lost the underlying patent infringement suit – an assumption the Court cannot make on this pre-discovery motion. Likewise, the Court cannot assume that Defendants would have won their infringement suit, and therefore cannot grant summary judgment for Defendants on Count Five either.

A. Plaintiffs' Motion Must Be Denied Because the Settlement Agreements Permitted the Generic Competitors to Enter the Memantine Market Earlier Than If Defendants Had Won Their Patent Infringement Suit

The relevant provision of the pediatric exclusivity statute is 21 U.S.C. § 355a(c)(1)(B)(ii), which states that, if the brand-name manufacturer's pediatric studies are accepted, then:

> if the drug is the subject of a listed patent for which a [Paragraph IV] certification has been submitted . . . , **and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed,** the period during which an application may not be approved under . . . [21 U.S.C. § 355(j)(5)(B)] shall be extended by a period of six months after the date the patent expires (including any patent extensions).

(Emphasis added.)

This means that, where the name-brand drug manufacturer being awarded the pediatric exclusivity period is faced with a Paragraph IV Certification (asserting that the name-brand drug's patent is invalid or will not be infringed by the generic competitor), if the name-brand manufacturer *wins* its patent infringement suit, the FDA may not approve any generic competitor until six months after the expiration of the patent's term.

As discussed above, in the ordinary course, a Paragraph IV Certification gives the brand-name manufacturer the right to sue the generic manufacturer within forty-five days for patent infringement. 21 U.S.C. § 355(j)(5)(B)(iii). Bringing suit triggers a thirty-month stay during which the FDA may not approve the generic manufacturer's ANDA unless the brand-name manufacturer loses the infringement suit, in which case the ANDA is approved immediately. *Id.* § 355(j)(5)(B)(iii)(I). If the brand-name manufacturer wins the suit, the ANDA may not be approved until after the patent expires. *Id.* § 355(j)(5)(B)(iii)(II). If the suit is not resolved within the thirty-month period, the ANDA is automatically approved at the end of the thirty months unless the court extends the stay. *Id.* § 355(j)(5)(B)(iii); *see also Actavis*, 133 S. Ct. at 2228.

The parties agree that, had Defendants prevailed in their patent infringement litigation against the Generic Competitors, no generic competitor would have been able to enter the memantine market until April 11, 2015 (if Forest did not obtain pediatric exclusivity) or October 11, 2015 (if Forest obtained pediatric exclusivity). Had Defendants lost the litigation, the patent would have been declared invalid or not infringed and the Generic Competitors could have entered the market immediately, regardless of whether Forest obtained pediatric exclusivity or not. Had the litigation not resolved before the end of the thirty-month stay, the Generic Competitors' ANDAs would have become effective at the end of the thirty months unless the court extended the stay, again regardless of whether Forest obtained pediatric exclusivity.

Once Defendants settled with each Generic Competitor, the patent infringement litigation was dismissed, meaning that there was never a judicial determination about the validity or scope of the '703 Patent. Therefore, once the thirty-month stay period expired, the FDA proceeded to give final approval to each of the Generic Competitors' ANDAs. But for the terms of their settlement agreements with Defendants, each Generic Competitor would have been able to enter the memantine market as soon as the FDA gave final approval to its ANDA.

Plaintiffs argue that the settlement agreements were a *per se* restraint of trade because, had the parties never settled, the ANDAs would have been automatically approved at the end of the thirty-month stay, and the Generic Competitors would have been able to enter the market as soon as they received approval from the FDA.

But Plaintiffs' position relies on several faulty assumptions. First, it assumes that the court handling the infringement action would not have extended the thirty-month stay, as it is empowered to do under the terms of Section 355(j)(5)(B)(iii). Second, it assumes that Defendants would not have *won* the infringement suit had they continued to pursue the action

instead of agreeing to settle – a proposition for which it puts forward no evidence whatsoever. If Defendants had won, no ANDA would have been approved until after the expiration of the patent on April 11, 2015 (if Forest did not obtain pediatric exclusivity) or October 11, 2015 (if it did).

By settling with each of the Generic Competitors in the manner that they did, Defendants reduced the number of potential dates of the entry of generic competition down to two: (1) January 11, 2015 (if Forest did not obtain pediatric exclusivity) and (2) July 11, 2015 (if Forest obtained pediatric exclusivity). Both of these dates were *earlier* than would have been the case if Defendants prevailed in their patent infringement action, and later than if Defendants lost the action or if the action failed to resolve before the expiration of the stay. They were, in the truest sense, a compromise. Defendants avoided the risk of the patent's being declared invalid, which would have allowed generic competition to start immediately after the lawsuit, and the Generic Competitors avoided the risk of Defendants winning the infringement action, which would have kept them out of the market until April 11, 2015, or possibly October 11, 2015.

Plaintiffs are correct that, once the FDA approved the Generic Competitors' ANDAs, nothing stopped them from entering the market other than their agreements with Defendants. But the FDA was only able to approve the ANDAs when it did *because* the parties had settled the infringement suit and allowed the thirty-month stay to elapse. If the court had extended the stay until the end of the litigation, or if Defendants had prevailed, the ANDAs could not have been approved until much later. Indeed, some of the letters approving the ANDAs explicitly state that the settlement of the infringement litigation is what allowed the FDA to grant approval to the ANDA when it did: "You also notified the [FDA] that [the parties] agreed to the dismissal of this

case, making your ANDA eligible for approval." (Litvin Decl. Ex. 4, Dkt. No. 149-3 (FDA Approval Letter to Dr. Reddy's).)

Because the settlement agreements allowed the Generic Competitors to enter the memantine market *earlier* than if Defendants had won their patent infringement action (regardless of whether Forest obtained pediatric exclusivity or not), the agreements were not *per se* restraints of trade in violation of the Sherman Act. Plaintiffs have cited no case where an agreement to potentially allow *greater* competition has been declared a *per se* restraint of trade in violation of Section 1 of the Sherman Act.

A practice is considered *per se* anticompetitive when "experience with a particular kind of restraint enables the Court to predict with confidence that the rule of reason will condemn it." *Arizona v. Maricopa Cty. Med. Soc.*, 457 U.S. 332, 344 (1982). Conduct that is subject to *per se* analysis is invalid *regardless* of any procompetitive justification that may exist in a particular case. *Id.* at 351.

However, agreements to settle patent infringement litigation like those at issue here are not *per se* anticompetitive, because the Court is required to evaluate the potential procompetitive effects of such agreements. In *Actavis*, the Supreme Court stated that, in general, "settlement on terms permitting the patent challenger to enter the market *before* the patent expires . . . bring[s] about competition . . . to the consumer's benefit." 133 S. Ct. at 2234 (emphasis added). Evaluation of such procompetitive effects would be unnecessary if these agreements were subject to *per se* rules. Such settlements are, instead, reviewed under *Actavis*'s rule-of-reason analysis. *See id.* at 2236.

Plaintiffs' reliance on *Brulotte v. Thys Co.*, 379 U.S. 29 (1964), is, therefore, misplaced. *Brulotte* involved a royalty agreement that projected beyond the expiration of the patent term,

which the Supreme Court concluded was an attempt to preserve the patent monopoly after expiration of the patent and thus a *per se* violation of the patent laws. *Id.* at 31-33. As discussed, in the event that Forest did not obtain pediatric exclusivity, the settlement agreements would not have delayed entry of generic competition beyond the end of the '703 Patent's term. Once Forest obtained pediatric exclusivity, the settlements delayed generic entry beyond the expiration of the patent but not beyond what would have happened automatically under the Hatch-Waxman Act in the event Defendants had won their infringement suit. Neither scenario would result in a *per se* illegal extension of the '703 Patent's monopoly.

Whether the settlement agreements were anticompetitive or procompetitive will depend on several complex factual questions that cannot be decided on summary judgment. As the Court indicated in its earlier decision denying Defendants' motion to dismiss, Plaintiffs may have a viable Section 1 claim under the theory that the settlements contained unlawful reverse payments to Defendants' Generic Competitors in exchange for dropping their challenges to the validity of the '703 Patent. *See Namenda III*, 2016 WL 4992690, at *12-*15. Such a claim, however, will depend on the presence of "evidence suggesting that the settlement agreements did, in fact, delay generic entry," which will presumably require proof that the '703 Patent would likely have been found invalid or not infringed by the Generic Competitors, or that the litigation would have continued past the expiration of the thirty-month stay, or that the reverse payment at issue was large or unexplained. *Id.* at *15. Resolution of these questions under a rule-of-reason analysis will require significantly more factual development than what is reflected in the present pre-discovery record.

Plaintiffs' motion is, therefore, DENIED.

B. Defendants' Cross-Motion Must Be Denied Because Plaintiffs May Have a Viable Section 1 Claim Under *Actavis*

By the same token, Defendants' cross-motion seeking dismissal of Count Five's Section 1 claim must also be denied. Although Plaintiffs cannot proceed on a *per se* theory, Count Five also presents a viable Section 1 claim under the rule-of-reason analysis set forth in *Actavis*, making summary judgment on that count inappropriate.

Defendants argue that, as a matter of law, their conduct was not anticompetitive under any standard because their settlement agreements with the Generic Competitors are not what prevented generics from entering the market. Defendants argue that the Generic Competitors' ANDAs were only "tentatively" approved by the FDA, and, because the '703 Patent was never declared invalid, it was the lack of "final" approval from the FDA that prevented the Generic Competitors from entering the market, not the operation of the settlement agreements. Defendants argue that, upon expiration of the '703 Patent, the still-unapproved ANDAs with their Paragraph IV Certifications automatically "converted as a matter of law" to Paragraph II Certifications, or else had to be refiled as Paragraph II Certifications, citing *Ranbaxy Labs. Ltd. v. FDA*, 307 F. Supp. 2d 15 (D.D.C.), *aff'd*, 96 F. App'x 1, 20-21 (D.C. Cir. 2004).

That argument is incorrect. There is nothing "tentative" about the FDA approval of the Generic Competitors' ANDAs. (*See, e.g.*, Litvin Decl. Ex. 6, Dkt. No. 149-5 (FDA Approval Letter to Amneal).) Each approval letter acknowledges the continued existence of the '703 Patent and notes that the patent infringement suit brought by Defendants had been dismissed. (*E.g.*, *id.*) It then grants approval to the ANDA "effective on the date of this letter," with no indication that market entry must be delayed until the expiration of the patent or the pediatric exclusivity period. (*E.g.*, *id.*)

As a matter of law, once the ANDA was approved, each Generic Competitor was "no longer under an obligation to amend its patent certification," even after the '703 Patent expired. *AstraZeneca AB v. Impax Labs., Inc.*, 490 F. Supp. 2d 368, 380 (S.D.N.Y. 2007). The Generic Competitors' existing Paragraph IV Certifications did not "convert" to anything upon expiration of the '703 Patent; their approvals were already final. Therefore, it was only through operation of the settlement agreements that the Generic Competitors were prevented from entering the memantine market immediately upon receipt of FDA approval. As discussed, the settlement agreements also allowed the FDA to approve the ANDAs prior to the expiration of the patent.

Whether these settlements were ultimately procompetitive or anticompetitive is a question that will be determined at trial under the framework established in *Actavis*, 133 S. Ct. at 2234. Therefore, Defendants' cross-motion is also DENIED.

Conclusion

For the foregoing reasons, Plaintiffs' motion for collateral estoppel and partial summary judgment on Count One (Dkt. No. 134) is GRANTED IN PART AND DENIED IN PART. Plaintiffs' motion for partial summary judgment on Count Five (Dkt. No. 138) is DENIED. Defendants' cross-motion for partial summary judgment dismissing Count Five (Dkt. No. 161) is DENIED. Plaintiffs' motion for leave to file a sur-reply in support of its motion for partial summary judgment on Count Five (Dkt. No. 230) is DENIED.

The Clerk of the Court is directed to remove Dkt. Nos. 134, 138, 161, and 230 from the Court's list of pending motions.

Dated: May 23, 2017

Chief Judge

BY ECF TO ALL COUNSEL

EXHIBIT

396

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
Civil Action No. 1:15-cv-07488-CM

IN RE NAMENDA DIRECT PURCHASER ANTITRUST LITIGATION

VIDEOTAPED DEPOSITION of ROBERT CARNEVALE, taken at Garwin Gerstein & Fisher LLP, 88 Pine Street, New York, New York, at 9:04 a.m., Wednesday, August 23, 2017, before Debra Stevens, Certified Realtime and Registered Professional Reporter and Notary Public of the State of New York.

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with -- well, do you know what alliance this is talking about?
A. I don't exactly know, but I am assuming that it is between [redacted] and Forest.
Q. Okay. Were you involved in more than one alliance agreement between Forest and [redacted]
A. No. There was one for a secondary supply that we had. None -- no other alliances that I was involved.
Q. For what drug was that?
A. [redacted]
Q. How did that come about?
A. Back in [redacted] or around there, at some point, we bought a company called [redacted] And we had a supplier for [redacted] a primary supplier. And part of our strategy back in the day was to dual source all our products.
So [redacted] was a potential secondary supplier for Forest.
Q. Who were the other potential

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secondary suppliers?
A. We looked at a number of companies. [redacted]
Q. Did you prepare analysis for those other three companies?
A. We did analysis for other companies, but it's a little bit different than what you do for -- if you are comparing. If I am comparing to something, it is different than what you do for, say, the Lexapro authorized generic.
Q. Talking about the [redacted] deal, did David Solomon make the decision to pursue an alliance agreement with [redacted]
A. Yes. David was the head of business development, so he signed off on all deals.
Q. Do you know why he chose [redacted] as opposed to the other companies that you mentioned?
MS. O'SHAUGHNESSY: Object to form. Calls for speculation.

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A. I mean, I don't know exactly why. I can tell you that we -- in part of our secondary sourcing, you know, strategy, we looked at all those other companies as well. And we also did site visits to India to look at the companies.
I can tell you from those visits we spent a week in India in four different cities where they are and visited their facilities. And [redacted] probably had the best looking and best facility for a supplier.
And since this was an antibiotic, you needed to have a facility that was, you know, very clean and qualified and was able to make antibiotics in the way we wanted it to be made.
Q. But you don't know why Dr. Solomon chose [redacted]?
A. I am assuming he chose them because they were a qualified supplier.
Q. Okay.
A. Or the best qualified supplier out of all the other ones.
Q. Can you turn to the first page

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of the document? There is a bottom email --
A. Yes.
Q. -- from [redacted] to David Solomon. Do you see that?
A. Yes.
Q. It says, second paragraph, [redacted]
Do you see that?
A. Yes.
Q. Now, the earlier email that we looked at, it references another email. Do you know if that, the memantine patent litigation was referenced when you approached [redacted]
A. I don't.
MS. O'SHAUGHNESSY: So --
Q. You don't know one way or another?
MS. O'SHAUGHNESSY: I will object to the question. Object to

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sourcing?
MS. O'SHAUGHNESSY: Object to form.
A. I didn't consider anything. No. That wasn't what we were doing there. We were just looking for a secondary supplier for the product.
Q. Would Forest enter into a secondary supply agreement with a company that was in litigation against it?
MS. O'SHAUGHNESSY: Object to form.
A. I would think -- and I am assuming, and I don't know the answer to this. But I would say that they would probably want not to be in litigation with somebody that is a supplier. They would probably want to make sure that they -- they resolve that before they do that. Just not probably a good business to do that. But I can't tell you.
Q. Then the next email, the top email in here is from David Solomon, the same day, to [redacted] Again, you are cc'd on here, saying that he would be happy to

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meet with [redacted] and they were going to set something up. Right?
A. Yes.
Q. Sorry? Go ahead.
A. I just said it looks that way.
Q. The second paragraph there says, from Dr. Solomon, says, [redacted]
Do you see that?
A. Yes.
Q. Do you remember discussing that with David Solomon?
A. I don't. No.
Q. You don't know why he said that?
A. I would not want to speculate. I would imagine what I just said about not being, you know, in a business deal with someone you are in litigation with is probably, you know, a reason. But I can't tell you exactly why he wrote that.
Q. And again, you don't know why the Namenda patent litigation was brought

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up at all during these discussions?
MS. O'SHAUGHNESSY: Object to form. Calls for speculation.
A. No, I don't know why exactly.
Q. Do you know if settlement discussions were going on in May 2008 between the companies?
A. I don't know. I can only speculate that they may have been.
Q. Do you know if other companies had settled patent litigation involving Namenda with Forest?
A. That I don't know.
Q. After May 2008, do you know what happened in the [redacted], when the next contact was?
MS. O'SHAUGHNESSY: Object to form. Vague.
A. What happened was we ended up signing a term sheet with [redacted] to see if they could make the product for us. And then we moved into a -- actually, it was an MOA, not a term sheet. But it was an MOA, memo of understanding -- MOU.
And then -- to see if they could

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make product. And then we went to a term sheet.
Q. Did [redacted] end up manufacturing the product?
A. What I remember is they ended up manufacturing the small amount that we asked them to manufacture just to see if they could manufacture it. And they did that. But when they were able to -- when they wanted to scale it up, they were not able to do that. They had problems doing that.
Q. They did a validation batch or something like that?
A. I don't remember how far they got on that batch, the validation batch. If I remember correctly, there was problem with water in the API or something.
Q. You said you looked at the facility.
A. Yes.
Q. But it seemed like they would be able to do it, but in the end they weren't able to do it.
A. Yeah. The facility from an

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261. Do you see Section 6.1, under "Forest profit share"?
A. Yes.
Q. It says, [redacted]
-- I am going to strike this whole line. I will withdraw the questions. I think I am done.
Five minutes?
MS. O'SHAUGHNESSY: Are you passing the witness?
MR. LITVIN: Yes. I have no further questions for the witness.
MS. O'SHAUGHNESSY: Let's go off the record.
THE VIDEOGRAPHER: Time on the video monitor is 1:45 p.m. We are off the record.
(Recess.)
THE VIDEOGRAPHER: We are back on the record. Time on the video monitor is 2:03 p.m.
EXAMINATION BY
MS. O'SHAUGHNESSY:

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Q. Good afternoon, Mr. Carnevale.
A. Hi.
Q. I just have a few questions for you based on your prior testimony.
Do you remember a discussion earlier on the record about a site visit or a number of site visits that you did in India?
A. Yes.
Q. For secondary source suppliers?
A. Yes.
Q. Do I have that right?
And just to clarify, you said that you went to four different cities in India. Is that correct?
A. Yes.
Q. How many different potential secondary suppliers did you visit?
A. [redacted]
Q. Were you looking at each of those companies for secondary supply of ceftaroline?
A. Yes.
MS. NOTEWARE: Objection to

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form.
A. Yes. We were --
Q. Which products were you looking -- for which products were you looking at each of these companies for secondary supply?
A. [redacted]
Q. Were you looking at any potential secondary supply sources of [redacted] outside of India?
A. For [redacted]? I don't remember. I think it was mostly for those companies. [redacted]

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[redacted]
Q. You also testified there was a memorandum of understanding, an MOU between Forest and [redacted] Is that correct?
A. Correct.
Q. And what was the timing of that MOU? Do you recall?
A. I think it was around [redacted]
Q. Okay.
A. I could be getting my dates mixed up. [redacted].
Q. So you think the MOU was signed, is it fair to say, [redacted]
MS. NOTEWARE: Objection to the form.
A. Yes. Somewhere around the [redacted] Yes.

EXHIBIT 404

** H I G H L Y C O N F I D E N T I A L **

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

Civil Action No. 1:15-cv-07488-CM

----------x

IN RE NAMENDA DIRECT PURCHASER ANTITRUST LITIGATION

----------x

August 30, 2017

9:16 a.m.

Videotaped Deposition of RACHEL MEARS, taken by Plaintiffs, pursuant to Notice, held at the offices of White & Case LLP, 1221 Avenue of the Americas, New York, New York, before Todd DeSimone, a Registered Professional Reporter and Notary Public of the State of New York.

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ALSO PRESENT:

JD MARTINEZ, Videographer

THE VIDEOGRAPHER: We are now on the record. Good morning.

Today's date is Wednesday, August 30th, 2017, and the time is approximately 9:16 a.m. Please note that the microphones are sensitive and may pick up whispering and private conversations and cellular interference. Please turn off all cell phones or just place them away from the microphones as they can interfere with the deposition audio. Audio and video recording will continue to take place until all parties agree to go off the record.

This is media unit number one of the video-recorded deposition of Rachel Mears taken in the matter In Re Namenda Direct Purchaser Antitrust Litigation, filed in the United States District Court, Southern District of New York, civil action number 1:15-cv-07488. This deposition is being held at White & Case located at 1221 Avenue of the Americas, New York, New York.

My name is JD Martinez from the firm Veritext New York, I'm the videographer, and the court reporter is

Todd DeSimone from Veritext New York. I am not authorized to an administer an oath, I am not related to any party in this action, nor am I financially interested in the outcome.

Counsel and all present in the room and anyone attending remotely will now state their appearances and affiliation for the record. If there are any objections to proceeding, please state them at the time of your appearance, beginning with the noticing attorney.

MR. LITVIN: Dan Litvin, Garwin Gerstein & Fisher, for the direct purchaser class plaintiffs.

MR. OPPER: Joseph Opper for the plaintiffs.

MS. McDEVITT: Heather McDevitt of White & Case for defendants and the witness.

MS. DUVAL: Debora Duval from White & Case for the defendants and the witness.

MR. LITVIN: I believe we also have Dave Raphael on the line.

MR. RAPHAEL: David Raphael with Smith Segura & Raphael in Louisiana for the direct purchaser plaintiffs.

* * *

RACHEL MEARS,

called as a witness, having been first duly sworn, was examined and testified as follows:

EXAMINATION BY MR. LITVIN:

Q. Good morning, Ms. Mears. As you heard, my name is Dan Litvin. I represent the direct purchaser plaintiffs in this matter.

Have you ever been deposed before?

A. Yes, once.

Q. When was that?

A. I don't remember the exact date, but it was in connection with the town that I lived in in Westchester.

Q. It wasn't in connection with any of your employment responsibilities?

A. No.

Q. I'm just going to go over some ground rules for the deposition.

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specifics in that paragraph. I don't believe I had anything like that in mind.
Q. Do you know what the Lexapro BAG strategy is?
A. No.
MR. LITVIN: I think there are five minutes left on the video. I only have one more document. Maybe we should just change the video and probably wrap up.
THE VIDEOGRAPHER: We are going off the record 3:48 p.m., the end of media unit number four.
(Recess taken.)
THE VIDEOGRAPHER: We are returning to the record 4:04 p.m., the beginning of media unit number five.
BY MR. LITVIN:
Q. Ms. Mears, before the break, I believe you explained the reasons why the ceftaroline deal was important to you.
A. We discussed it, yes.
Q. Did any of David Solomon, Charles Ryan, Eric Agovino, or Herschel Weinstein express any other reasons why the ceftaroline deal might be important to

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Forest?
MS. McDEVITT: I will just caution the witness that if she can answer that question without revealing privileged information, you may do so; otherwise, I will instruct you not to answer.
A. I don't remember anything else.
Q. What was Forest's best-selling drug while you were negotiating with Orchid on a supply deal for ceftaroline?
A. It was either Lexapro or Namenda.
Q. Do you know if Orchid actually supplied any ceftaroline to Forest under the supply agreement?
A. It did not. Well, I don't want to say that. I don't remember the outcome of the development batches versus the validation batches, but I know that commercial supply wasn't ultimately initiated.
Q. And do you know how much Forest paid Orchid in connection with the ceftaroline deal?
A. I don't know in total how the

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payments played out against the operating plan for that term sheet.
(Mears Exhibit 26 marked for identification.)
Q. Ms. Mears, have you ever seen this document before?
A. I don't recall seeing this e-mail before.
Q. I'm sorry if I asked this before, but Robert Carnevale reported to you?
A. He did.
Q. Do you know who Jonathan Hahn is?
A. I believe he was an intern.
Q. For the Alliance Management Department or for Mr. Carnevale individually?
A. I believe he was an intern at Forest.
Q. In the Alliance Management Department?
A. In our team. I don't remember exactly who he reported to or how.
Q. And do you ever recall

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receiving spreadsheets like the one attached to this e-mail?
A. I don't remember running these kinds of reports in ordinary course.
Q. And you don't remember this spreadsheet specifically? I'm looking on the fourth overall page of the exhibit.
A. As I mentioned, I don't recognize this document.
Q. Can you turn to the fifth page of the document.
A. Yeah.
Q. Do you see --
A. I'm sorry, just to be clear, starting at the top, Inwood?
Q. Yeah, the first two lines are Inwood.
A. Okay.
Q. Do you see seven lines down there is a blue column that says Lexapro?
A. A blue line, a blue row?
Q. A blue row, yeah.
A. I do.
Q. The next column says Lundbeck, and the next column says "Letter agreement

cephalosporin, and we had a primary supplier in [redacted], and the ceftaroline sourcing project in terms of looking for second source was something, as I mentioned, we did for all of our drugs, but it was particularly challenging in the antibiotics space.

I mean, antibiotics are notoriously underfunded. It is hard to find supply partners. It is hard to find supply partners that have the right size facility and sterile capabilities that are stable. And Orchid was one of those candidates. And so I was very interested in having a positive business relationship on ceftaroline with Orchid, as was the folks that worked on this initiative for ceftaroline.

And so what happened was that generic companies that were peers to Orchid had started to settle, and that was out and known, and I reference in this paragraph, and I wanted C.B. to understand that we had concerns about placing a program so important to us with a company that we

hadn't known previously in business at a time when they were adverse to us in a very serious way, and it was my way of showing him your peers are taking a different direction, they are not adverse to us in that respect, and I wanted him to not be adverse to us, and I wanted Orchid and that supply chain to succeed.

And we had done a decent amount of diligence on antibiotics and other options and thought that this was a good possibility to get a backup supplier and potentially even a primary supplier for ceftaroline, because the other manufacturer, [redacted], was based in Europe, and we had done our research, and pricing would typically be better sourced out of India.

So there was a strong business motivation to have a positive relationship with Orchid, but we were concerned that the adversarial aspects of that relationship would detract from the go-forward strategic relationship that we wanted to have with them on supply.

It was also not something we had typically done. We had never second-sourced an antibiotic, I believe, to my knowledge, previously. So for us, it was a matter of first strategic importance, and that was what I was trying to do in that paragraph.

MS. McDEVITT: Thank you. I have no further questions.

MR. LITVIN: Nothing here.

THE VIDEOGRAPHER: We are going off the record. The time is 4:16 p.m.

MS. McDEVITT: I'd like to mark the transcript highly confidential under the protective order.

[TIME NOTED: 4:16 p.m.]

_____
RACHEL MEARS

_____
Subscribed and sworn to before me this _____ day of _____, 2017.

_____
Notary Public

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EXHIBITS

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CERTIFICATION

I, TODD DeSIMONE, a Notary Public for and within the State of New York, do hereby certify:

That the witness whose testimony as herein set forth, was duly sworn by me; and that the within transcript is a true record of the testimony given by said witness.

I further certify that I am not related to any of the parties to this action by blood or marriage, and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 31st day of August, 2017.

Todd DeSimone

_____

TODD DESIMONE

* * *

ERRATA SHEET
VERITEXT/NEW YORK REPORTING, LLC

CASE NAME: IN RE NAMENDA
DATE OF DEPOSITION: 8/30/17
WITNESS' NAME: RACHEL MEARS

PAGE/LINE(S)/	CHANGE	REASON
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RACHEL MEARS

SUBSCRIBED AND SWORN TO BEFORE ME THIS_____DAY OF_____, 2017.

_____
NOTARY PUBLIC

MY COMMISSION EXPIRES_____

EXHIBIT

438

UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF NEW YORK

* * * * * * * * * * * * * * *

IN RE: *

NAMENDA DIRECT PURCHASER * C.A. 1:15-cv-07488-CM

ANTITRUST LITIGATION *

* * * * * * * * * * * * * * *

** HIGHLY CONFIDENTIAL **

Videotaped Deposition of ERNST R. BERNDT, Ph.D.

Thursday, November 2, 2017

9:07 a.m.

White & Case LLP

75 State Street - 24th Floor

Boston, Massachusetts 02109

---------- Janis T. Young, RDR, CRR ----------

Registered Professional Reporter

Q. Namenda XR actually launched in mid-June, but you chose to exclude forecasts from June; is that right?

A. For that calculation, yes; and in part because IMS data typically comes -- at least the NPA data, becomes available about ten days after a week ends.

And so there probably was minimal, if any, data available in July 2013 that talked about the first few weeks of data. I'll take your representation; I may have gotten the launch date wrong.

Was it June 14, you're saying, 2013?

Q. It was mid-June, 2013.

A. So early August would be the first time you would get some monthly data.

Q. And when you keep referring to IMS data, I want to make sure that we're clear. You're not talking about IMS data in terms of the actual projections; right? You're talking about the IMS data that was included in Forest's projections; correct?

A. I'm including -- what I'm referring to is that when Forest made its internal projections, to my understanding it was based on data they purchased

from IMS.

And IMS has several data sources. In the context of making these monthly forecasts, I presumed that they used a monthly data source from IMS. But they may have also used some of their weekly data forecasts.

Q. And you include in Exhibit D some forecasts that are dated on the same date; correct?

A. Yes, particularly when they had some different information.

So, for example, I have two of them on September 30, and they have different numbers. And I have two of them on August 20, and they have some different numbers.

And you have three on October 8; correct?

A. And on two of the three -- there are two that have the same numbers. And I included a second one on October 8, as you see in my footnote there, that the metadata suggests that that document was created in 2012, was last printed on that date, so I don't know exactly when it was made, but in order to err on the side of caution of forecasted rates, since that's a forecast that has a [redacted] conversion rate, which is on the high end, I

included it.

Q. And in your definition of recent forecasts, the end date was pre February 14, 2014; correct?

A. Yes.

Q. And why did you choose that date as the end date?

A. That was the date that Forest announced its hard switch strategy. There may have been some forecasts after October 29, between February -- between October 29, 2013, and February 14 of 2014; but since the decision was made internally, announced internally to pursue the hard switch on October 18 I believe the date was, I didn't include many forecasts beyond that, because they would be tainted by knowledge of the internal decision.

Q. And, sir, when you refer to the internal decision being in October 2013, I believe you discuss that in Paragraph 37 of your original report; correct?

A. Yes.

Q. And you cite to one document for that proposition; is that right?

A. That is correct.

Q. And that is an October 18, 2013 email from Gary Samoriski; is that correct?

A. Yes.

Q. Who is Gary Samoriski; do you know?

A. No, I do not.

Q. Was he deposed in this action?

A. I do not know.

(Marked, Exhibit 10, email chain, top email Bray to Samoriski, 1-21-14, FRX-NY-01576623 - 624.)

Q. Sir, I'm handing you what's been marked as Exhibit 10. This is an email from -- the top email is from June Bray to Gary Samoriski dated January 1, 2014. Do you see that?

A. Yes, I see that.

Q. And the first email in time, the second is from Gary Samoriski, and the second paragraph down says, [redacted] Do you see that?

A. Yes. It's not clear to me whether that means whether the announcement of the decision or the decision already -- having moved forward with the transition itself.

Q. And sir, you understand Brent to mean Brent Saunders, the CEO of Forest?

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number that you gave earlier to me regarding a typical generic scenario with an AG and a first filer on the market together and a 180-day exclusivity period?

MR. LUKENS: Object to the form, misstates his testimony.

A. If "typical" excludes fierce competitors like Teva, then that is consistent. But again, as I state numerous times in my report, [redacted] is a very aggressive discounter, and that this occurred, I think, is not a surprise to those who are really good -- who really understand the industry.

Q. Jefferies is a knowledgeable industry analyst; correct?

MR. LUKENS: Object to form, foundation.

A. I believe they are a substantially pharmaceutical portfolio, yes.

Q. And Jefferies says here this generic-to-price ratio is "[redacted]"; correct?

A. That's what it says.

Q. You can put that aside.

I want to turn to Paragraph 39 of your rebuttal report. Let me know when you're at

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Paragraph 39.

A. I'm there, sir.

Q. You say here -- I'm trying to find Paragraph 39.

The bottom of Paragraph 39 on Page 32, you say, quote, "I am aware of no evidence, and Mr. Green cites none, that reveals the purpose for which the projections were prepared."

Are you referring to the Lexapro profit-share projections prepared by Forest?

A. Yes.

Q. Is it your testimony that there's no evidence in this record that the projections Mr. Green cites to were actually used as part of Forest's analysis in amending the Lexapro agreement with Mylan?

MR. LUKENS: Objection to form. Misstates his report.

MR. ADAM: I asked him a question if that is his testimony. I'm not misstating the report.

Q. I'm asking, is it your testimony that there's no evidence in this record that the projections Mr. Green cites that Forest relied on in negotiating the Lexapro amendment were actually used

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as part of Forest's analysis during the negotiations with Mylan of the Lexapro amendment?

MR. LUKENS: Objection to the form, misstate his testimony.

Q. You can answer.

A. What I stated here was Mr. Green has not provided any evidence that these particular projections were ones that were made in the normal course of Forest's forecasting, and as we've seen from the Namenda case, those forecasts were done with great care, they considered analogues, they were done over a period of more than a year, and he cites -- I state here, nothing that reveals the purpose for which these particular projections were prepared.

Q. Did you review Mr. Carnevale's deposition testimony in this case, which Mr. Green does cite?

A. I don't remember reviewing -- I don't think I cited; do I?

Q. I'll represent to you it's not on either of your Docs Relied Upon list.

So you didn't review it; correct?

A. Not that I can recall, sir.

Q. So in forming this opinion that you're not aware of any evidence that Forest actually relied on

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these projections, you're making that comment in the context of not having reviewed the testimony of Mr. Carnevale; is that fair?

A. I think that's fair.

Q. And it would be the same for the testimony of Mr. Solomon; correct?

A. I may have reviewed his testimony, but I don't remember it. I don't think I relied on it.

Q. I'll represent to you that I don't see it here in either of your Documents Relied Upon lists. Let me just check the first report one more time.

So you don't know if Mr. Solomon or Mr. Carnevale have testified that they did indeed rely on these Lexapro projections in negotiating the Lexapro amendment with Mylan; correct?

MR. LUKENS: Object to form.

A. I don't know whether they did, and I don't know whether they relied on them in an irrational way or whether -- I just don't know.

Q. You haven't reviewed any documents in this case that suggest that the forecasts, the Lexapro forecasts, were circulated amongst Robert Carnevale, David Solomon, Rachel Mears and others in preparation for a meeting with Mylan; is that correct?

MR. LUKENS: Object to form.
A. I don't recall that.
Q. If such a document exists, that would change your opinion here as to whether or not you're aware of any evidence that these Lexapro forecasts were actually used in negotiating the Lexapro amendment with Mylan?
MR. LUKENS: Object to form and misstates what he said in the report.
Q. You can answer.
A. It could change my opinions; I'd have to see the documents and understand their context.
(Marked, Exhibit 24, email chain, top email Carnevale to Solomon, 3-14-10, FRX-AT-004407590 - 595.)
Q. The court reporter has just handed you a document bearing the Bates number FRX-AT-044079590. It's a chain of emails --
A. I think you misstated that. There's an extra number 9 there.
Q. 04407590.
A. Correct.
Q. And the email is titled '[redacted] Do you see that?
A. Yes.

Q. And it says, "[redacted]" and has a list of bullets, and one of which, the second one, is "[redacted]." Do you see that?
A. Yes.
Q. And if you look at the attachments for that email, this email is dated March 14, 2010, one of the attachments here is '[redacted]"
MR. SORENSEN: I don't have any attachments.
MR. LUKENS: I object. He's referring I think to the line that says "Attachment," David.
MR. SORENSEN: Oh, I'm sorry.
MR. LUKENS: It's notable that the attachments here are withheld for privilege. I think we can put that in the record.
MR. ADAM: You might want to check this document after.
THE WITNESS: I'm sorry; could you repeat that? I didn't hear you.
MR. LUKENS: I just said the only attachments on here are withheld for privilege, so the document that he's handed to you has a statement that says "attachments" that lists named attachments, and the only documents behind it are

withheld for privilege. That's what the document has on it.
MR. ADAM: Fair enough.
Q. The attachment to this email, [redacted]n. Do you have any reason to believe that that's not accurate?
MR. LUKENS: And I'll object to the form. You're representing the attachment to this document is that? I mean, he has no reason to believe anything, because it says withheld for privilege.
So he can answer the question, but you're making a representation here that's not backed up by the document you're showing the witness.
MR. ADAM: I'll represent to you, counsel, that these documents have all since been produced. The version that we're looking at now that says "privileged" on the attachments, plaintiffs have those documents now.
MR. LUKENS: That's fine, but Dr. Berndt doesn't have them.
MR. ADAM: I'm not asking about the

contents of the attachment --
MR. LUKENS: You're asking him to characterize the attachment. If you want to show him the attachment, that's fine, but....
Ask him what you want.
Q. Dr. Berndt, do you have any reason to believe that the attachment to this email, titled '[redacted]
A. I have no reason to believe that or not to believe it.
Q. But you see it's listed here as an attachment; correct?
A. I see a listed attachment, yes.
Q. If you go to the second email, it says, "[redacted]." Did I read that right?
A. Yes.
Q. And this is in the context of an email titled '[redacted] about an upcoming meeting with [redacted] correct?
MR. LUKENS: Objection to form. You're asking him to agree that it says that?
Q. You can answer.
A. I see from the first email dated January 20

EXHIBIT

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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

IN RE NAMENDA DIRECT PURCHASER ANTITRUST LITIGATION	)	Civil Action No. 1:15-cv-07488-CM

****HIGHLY CONFIDENTIAL****

30(b)(6) DEPOSITION OF

DAVID SOLOMON

New York, New York

Thursday, September 7, 2017

Reported By:

CATHI IRISH, RPR, CRR, CLVS, CCR

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his individual capacity, is my understanding.

MR. TOTO: Understood but the question was in the context of the topics. So if you want to be clear you're asking him in his individual capacity, I think that might be helpful as well as we go along today but why don't we see how it goes.

MR. LETTER: Sure.

THE WITNESS: Again, I'm --

BY MR. LETTER:

Q. Do you have any reason to doubt the facts in this document, sir?

A. No, I clearly read it and signed it three years ago so I'm sure at the time I read it and understood it.

Q. The next sentence after that sentence that we were just referring to starts with those [redacted] were. Do you see that?

A. Yes.

Q. [redacted] Do you see that?

A. Yes.

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Q. Dropping down to paragraph 15, which has a heading [redacted] Do you see that?

A. Yes.

Q. Then in the first sentence after the heading, there's a mention of first [redacted]. Do you see that?

A. Yes.

Q. Do you have an understanding of what first filer ANDA exclusivity is, sir?

A. Yes.

Q. And can you tell me please?

MR. TOTO: Objection, calls for legal conclusion but you may answer.

THE WITNESS: So under the Waxman Hatch legal regime, generic companies that file their ANDA -- are the first to file an ANDA together with a paragraph IV certification challenging the validity or enforceability of a patent are entitled if they are successful to six months of exclusivity. So they have an ability to launch in advance of other generic filers who come along and file their

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ANDAs later.

BY MR. LETTER:

Q. So the first to file ANDA exclusivity is actually an exclusivity as to other generics; correct?

MR. TOTO: Objection, calls for legal conclusion. Object to form.

THE WITNESS: So the generics who have this first filer exclusivity are entitled to launch while other generics are not.

BY MR. LETTER:

Q. And do you see that that sentence continues -- actually let me back up.

[redacted]

A. Yes.

Q. [redacted]?

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MR. TOTO: Objection, the document speaks for itself.

THE WITNESS: Again, I can read the sentence for you. It's been awhile and I see what the document says but I don't personally recall which generic filers were first or who filed when or, you know, it's been a long time.

BY MR. LETTER:

Q. But again, no reason to doubt the accuracy of the document?

A. I'm sure at the time I read it and as I said, understood it.

MR. LETTER: Sir, you may put that document aside.

I'm going to show you a document that's being marked as Solomon Exhibit 3.

(Solomon Exhibit 3, document Bates stamped FRX-AT-04134770, marked for identification.)

BY MR. LETTER:

Q. Sir, while you're reviewing that document I will read into the record that

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putting up a 30(b)(6) representative that has knowledge that's not in the possession of the company. But I am going to let him answer to the best of his ability and we've done our best to refresh him on this topic with the information that is in possession, custody and control of my client today.

MR. LETTER: I think this is a fairly innocuous question so I'm going to ask it again.

BY MR. LETTER:

Q. Are you aware that when Forest launched an authorized generic immediate release product it did so in conjunction with as many as five other generic immediate release Namenda products?

A. So to answer your question, I really know nothing about the launch of Forest's -- Actavis's generic Namenda. I had left the company and I was not involved or had any information about it.

Q. Sir, one of the topics -- and feel free to refer to Solomon Exhibit 1

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again -- one of the topics for examination that you were designated by Forest is Forest's efforts to develop, manufacture, prepare for commercial marketing and ultimately launch authorized generic Namenda.

Sir, you are aware that was one of the topics you were designated by Forest; correct?

A. Okay.

Q. And you did nothing to educate yourself about the actual launch of Forest's authorized generic Namenda?

MR. TOTO: Object to form.

THE WITNESS: I have not done any investigation into the launch of products that happened, you know, significantly after I left the company.

MR. LETTER: Sir, I'm going to show you a document that's being marked as Solomon Exhibit 5.

(Solomon Exhibit 5, FDA Listing of Authorized Generics, marked for identification.)

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BY MR. LETTER:

Q. While you're reviewing that, sir, I will for the record note that this is a printout from the FDA's website with a list of authorized generics as of June 30, 2017. Let me know when you've had an opportunity to review, sir.

A. Again, I've taken a quick look.

Q. Do you recognize this document, sir?

A. No.

Q. Do you have occasion to look at the FDA's website?

A. No.

Q. So you're not aware that they keep a list of authorized generics?

A. No.

Q. Sir, are you aware of something called an annual report that is submitted with a new drug application?

A. I've heard the term annual report but I really don't know much about it. That would have been handled by regulatory people.

Q. And that would come from Forest

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to the FDA; correct?

A. I think so.

Q. And it behooves Forest to be honest and accurate with the FDA; correct?

A. I believe Forest made every effort to be honest and accurate with the FDA.

Q. Sir, if you see on that first page of FDA authorized listing of generics, there's a note and it says this list was created from FDA's database of annual reports submitted to FDA. Do you see that?

A. No, where is it?

Q. First page under note, first sentence.

A. Okay.

Q. Do you see it now?

A. Uh-huh.

Q. I'd ask you to turn to page 3 of the document, there is an entry number 157 in the middle of the page for Carafate tablets?

A. Okay.

Q. And in the column heading NDA

Applicant Name, it says Forest Laboratories, Inc. Do you see that?
A. I see that.
Q. And then the next column over is date authorized generic entered the market.
Do you see that?
A. Yes.
Q. And for that entry of Carafate it's November 1, 1996.
Do you see that?
A. Yes.
Q. Sir, if you would turn to the next page, which I believe is page 4 of the document, there's an entry in line 392.
Do you see that?
A. Yes.
Q. For a drug called Flumadine?
A. Yes.
Q. And the NDA applicant under that entry is Forest Laboratories, Inc.; correct?
A. Yes.
Q. And the date authorized generic

entered the market was September 2002 to September 2003.
Do you see that?
A. Yes.
Q. If you would turn to the next page, which I believe is page 5 of the document, entry number 475, the drug name is Lexapro.
Do you see that?
A. Yes.
Q. And the dosage form is oral solution.
Do you see that?
A. Yes.
Q. And the NDA applicant name is Forest Laboratories, LLC.
Do you see that?
A. Yes.
Q. And the date authorized generic entered the market is March 26, 2015; correct?
A. Yes.
Q. And then the two entries below that, numbers 476 and 477 relate to Lexapro tablets; correct?

A. Yes.
Q. And the NDA applicant for those products was Forest Research Institute, Inc.; correct?
A. Yes.
Q. And the date of authorized entry was February 29, 2012; correct?
A. Yes.
Q. Turning over to the next page, which I believe is page 6 of the document, there is another Lexapro entry there, number 478.
Do you see that?
A. Yes.
Q. And again, the date of authorized generic market entry is February 29, 2012; correct?
A. Yes.
Q. Skip one page and go to page 8 of the document. There are entries 919 and 920. Let me know when you're there.
A. Uh-huh, I'm there.
Q. The propriety name is Tessalon; correct?
A. Yes.

Q. And the NDA applicant is Forest Laboratories, Inc.; correct?
A. Yes.
Q. One entry claims that the date the authorized generic entered the market was prior to January 1, 1999.
Do you see that?
A. Yes.
Q. And the next entry is April 1999 to April 2000.
Do you see that?
A. Yes.
Q. And then the last page of the document, entries 978 and 979, there are entries for Urso tablets.
Do you see that?
A. Yes.
Q. And the NDA applicant name is Forest Laboratories, Inc.
Do you see that?
A. Yes.
Q. And the date the authorized generic entered the market is July 6, 2009.
Do you see that?

A. Yes.
Q. Sir, by my count, and I'm going to confirm this again, one, two, three, four, five, there are five drugs for which Forest launched an authorized generic prior to being acquired by Actavis.
MR. TOTO: Are you really going to have the senior executive sit here and count up rows in a spreadsheet? Is that what you're going to waste his time on today?
MR. LETTER: Yes.
MR. TOTO: Okay, good to know.
THE WITNESS: Okay.
BY MR. LETTER:
Q. Is that, in fact, correct?
A. That this document reflects that, yes.
Q. So Forest launched an authorized generic five times prior to being acquired by Actavis for different drugs; correct?
MR. TOTO: Objection, calls for speculation, the document speaks for itself. You may answer.
THE WITNESS: Yeah, again, I'm

not, you know, this is not a document I'm familiar with but it -- we just walked through it so it suggests that there were those five authorized generics.
BY MR. LETTER:
Q. And you have no reason to doubt the accuracy of the document?
A. Documents on government websites are often inaccurate.
Q. Sir, you were designated to testify to topic 3 which specifically enumerates the authorized generics we just discussed.
A. Yes, but you're asking me to authenticate a document from the FDA website and I don't feel at all qualified to do that, nor can I vouch for the accuracy of a document on the FDA website. So if you ask me what the document says, I can agree with you about what it says. But if you're asking me is this an authenticated document and what is the significance of it being on the FDA website, I'm telling you I don't really

understand that and don't have a basis for judging it.
Q. Outside the context of this document, did you independently verify that Forest had launched these authorized generics as listed in topic 3?
A. So I'm familiar with several of these generics. There are a few that would have come through the acquisition of a company called Aptalis which happened soon before I left the company so I'm less familiar with those.
Q. So my question is simply did Forest, in fact, launch these authorized generics as listed in topic 3?
A. Did we launch them? I don't know. Did we sell them? At least for several of them I know we did.
MR. TOTO: And I object to that characterization of the document.
MR. LETTER: Sir, we've been going over an hour. Would you like to take a break?
THE WITNESS: Sure, we can take a break.

THE VIDEOGRAPHER: Stand by. The time is 9:15. We're going off the record. This will end media unit 1.
(Recess taken from 9:17 a.m. to 9:26 a.m.)
THE VIDEOGRAPHER: The time is 9:26. We're back on the record. This will be the start of media unit number 2.
MR. LETTER: Welcome back, Mr. Solomon. I'm going to show you a document that's been marked as Solomon Exhibit 6.
(Solomon Exhibit 6, document Bates labeled FRX-AT-01738735 through 835, marked for identification.)
BY MR. LETTER:
Q. Sir, while you're reviewing that I will read into the record, this was a document produced by Forest in this litigation to plaintiffs bearing the FRX-AT-01738735 through 835. Let me know when you've had an opportunity to review, sir.
A. I've just looked at the cover

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BY MR. ENGER:
Q. What did you mean when you said we had probably another [redacted] of legal expenses and associated costs left?
A. [redacted]
Q. [redacted]

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[redacted]?
A. I think it's an estimate but I think thereabouts is my understanding. Again, I'm not an expert. I wasn't running litigation, I wasn't paying the bills but that's a number I've heard.
Q. Who told you that number?
A. I don't remember.
Q. What's the factual basis behind that [redacted] dollar estimate?
A. That's an estimate that again, this is eight years ago so you're going to have to live with the best memory I've got.
Q. To sum it up, at the time of the [redacted], someone told you that litigation expense savings might be [redacted] and that's all you can tell me on this testimony -- on this subject?
MR. TOTO: Mischaracterizes his testimony --
THE WITNESS: I actually think that's somewhat dismissive of the last

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15 minutes we've been discussing it.
BY MR. ENGER:
Q. Tell me everything that you can remember about the [redacted] estimate of litigation savings at Forest.
A. That's a very open-ended question so I'm not going to answer it.
Q. You're not going to answer my question?
A. I can't --
MR. TOTO: He's saying he's incapable of answering (inaudible).
THE WITNESS: -- it's a ridiculous question. If you have a question, ask it.
MR. TOTO: He's incapable of answering your open-ended --
THE WITNESS: Tell me everything you know, [redacted]
///

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BY MR. ENGER:
Q. What's the factual basis for the [redacted] claim --
A. As I said to you, this was eight years ago. It's my recollection that that was what we were told at the time.
Q. Is there anything else that you would like to say on the record about the [redacted] litigation expense savings at this point in time?
MR. TOTO: Object to form.
THE WITNESS: I don't think it's my role to affirmatively state things for the record.
BY MR. ENGER:
Q. Did the [redacted] estimated litigation expense savings include attorneys' fees, costs, expenses, or was it some subset of those?
A. Again, I believe it was an estimate of the overall cost, would not have included our only internal costs. These would have been external costs so it wouldn't have included the time spent by external counsel but I believe that that

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that you were aware of estimates as high as [redacted] for the Medicaid savings?
A. Yeah.
Q. How were you made aware of those?
A. Again, there were -- there were various financials that were done at various points looking at this issue, looking at this issue. Again, not just for this product but for other products as well. So again, I don't have the specific but I recall numbers in that range.
Q. Do you recall a physical document from which you are remembering these numbers or was it just told to you?
A. There may be documents on this. I don't know.
Q. But --
A. You're talking about eight, 10, 12 years ago.
Q. I understand, but you're referencing a document so I mean you're referencing a figure so I have to explore the source for it.
A. Understood.
Q. You're not aware of any specific

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document that might have had that figure?
A. There may be documents.
Q. So sitting here today, do you have a firm understanding of where that [redacted] figure or what that [redacted] dollar figure is based on in terms of the factual -- the number itself?
A. I don't.
Q. Okay.
MR. LITVIN: That's all I have subject to stating on the record that I believe all of us for all the topics, all the 30(b)(6) topics, I reserve the right to leave the deposition open for a witness who is prepared to answer the questions more fully.
MR. TOTO: We oppose that. We -- our position is this witness was fully prepared, spent a nine-hour day here with limited breaks. There was a ton of inefficiency on your side using four questioners asking overlapping questions, spending almost an hour on questions that your side knows or

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should know or are prohibited by the stipulations we have in this case, asking the witness to count rows in spreadsheets and add five years to 2.5 years, et cetera. So that's our position.
I have maybe one question for the witness, maybe a couple.
EXAMINATION
BY MR. TOTO:
Q. Sir, you were asked, you'll recall, about the original [redacted]. Do you remember that question?
A. Yes.
Q. And do you recall you were asked some questions about product profit under that and particularly about the first [redacted]?
A. Correct.
Q. Was product profit defined the same way in both of those agreements?
A. [redacted]

[redacted]

EXHIBIT

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
----------x
THE PEOPLE OF THE STATE OF NEW YORK,

Plaintiff, New York, N.Y.

v. 14 Civ. 7473(RWS)

ACTAVIS, PLC, and FOREST LABORATORIES, LLC,

Defendants.
----------x
November 10, 2014
9:39 a.m.

Before:

HON. ROBERT W. SWEET,

District Judge

APPEARANCES

ERIC T. SCHNEIDERMAN
Attorney General for the
State of New York
Attorney for Plaintiff
BY: ERIC J. STOCK
ELINOR R. HOFFMANN
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WHITE & CASE LLP
Attorneys for Defendants
BY: JACK E. PACE III
MARTIN M. TOTO
J. MARK GIDLEY
PETER J. CARNEY
CHARLES C. MOORE
JAIME M. CROWE

THE COURT: Please be seated. Thanks very much.

First, my apologies. We got screwed up mechanically on when we were getting started. It is not the court reporters' fault, it is our fault, and I apologize for that.

Counsel, I think we've decided that the courtroom will be cleared of anybody except parties for the openings. I see a number of nice-looking people out there. Presumably, you all cannot identify all of those people as your people.

MR. STOCK: That is correct, your Honor.

THE COURT: Clear the court.

(Pause)

This will be about -- we will be about, my guess would be, 45 minutes.

MS. HOFFMANN: Your Honor.

THE COURT: Yes.

MS. HOFFMANN: Before you clear the court, there is a gentleman here I would like to move for his pro hac vice admission.

THE COURT: Yes. Sure. He is admitted.

MR. STOCK: Just, your Honor, on timing, I believe the case management order says 30 minutes for each side on openings.

THE COURT: OK. It will be an hour, folks.

MR. STOCK: Your Honor, one other housekeeping issue while we clear the court. Would it be all right if we created a transcript of the openings and ask the defendants to designate confidentiality the next day, the next business day?

THE COURT: Sure.

MR. GIDLEY: We're happy to do that, your Honor.

THE COURT: Sure. Now, I take it you all will certify that all these nice people are part of your entourage?

MR. STOCK: We see a number from our office, your Honor.

MR. GIDLEY: We see a number from the defendants as well.

THE COURT: Anybody here who is not with White & Case or the Attorney General?

(Pause)

OK. Thank you. Yes.

MR. STOCK: Shall I proceed?

THE COURT: Yes.

MR. STOCK: Thank you, your Honor.

Your Honor, in this case defendants are seeking to manipulate the regulatory system for pharmaceuticals and interfere with treatment plans for Alzheimer's patients all in an effort to unlawfully extend their monopoly and maintain inflated prices for their drugs. The goal of defendants' conduct is troubling in and of itself. They want to maintain high drug prices by preventing low-cost generic drugs from competing in the market.

But even more troubling is the means by which they seek to achieve this anticompetitive end. Defendants are pursuing a scheme known as a forced switch, which means that they intend to take patients who are currently taking a drug that works well and is about to be subject to generic competition and force these patients to switch to defendant's newer drug which won't be subject to generic competition for many more years to come. Your Honor, to accomplish this result, defendants are taking actions to prevent patients from obtaining the original version of their drug in order to ensure that the vast majority of them switch.

Your Honor, some business conduct has good and bad aspects. The forced-switch strategy, however, has absolutely no redeeming quality. It is antipatient, anticonsumer, it increases healthcare costs and it reduces patient and physician choice. Fortunately, your Honor, we have the opportunity to stop this indefensible scheme.

In this hearing, your Honor, we will provide evidence establishing that defendants, by pursuing a clearly anticompetitive objective and using a harmful and manipulative tactic in order to achieve it, have committed a classic violation of the antitrust laws, and we are prepared to provide evidence of that today and the rest of this week.

Now, before I go into further detail about our claims, I just wanted to introduce our team here representing the

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Hearing

A. It does say that. And in this form it specifically lists a number of drugs that are, for whatever reason, being restricted by the insurance company -- so antifungals, testosterone products, triptanes. And if I'm understanding this form and the intent of this form correctly, the physician is being asked to confirm that the medication is necessary for this individual because they have a specific condition that needs to be treated.
Q. And that, this form, you are right is for those conditions, but you in your practice have been required to sign prior authorization forms to get your patients Alzheimer's treatment, correct?
A. It's not common but I have, yes.
Q. Sir, as I understand your testimony on direct, are you saying that it is very unlikely that Namenda IR would be considered -- that you would consider it medically necessary for your patients?
A. That's right.
Q. So you don't see a market need for Namenda IR, correct?
A. That's true. With the exception that I would prefer that my patients who are currently taking Namenda IR should not be switched to another drug unless there is some foundation for doing so.
Q. That's your personal preference, correct?
A. That's my medical preference, yes.

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Hearing

Q. OK. But it's limited to your experience; you haven't conducted a survey of other physicians, correct?
A. No, I have not, but I believe that would be commonplace that if people are doing well on a particular drug or regimen of drugs, that there would be no reason to do changes that would impose an unnecessary risk to that individual.
Q. Doctor, do you think Namenda XR is a good new product, correct?
A. I believe so, yes.
Q. And I think you said on direct the clinical data is quite good on it, correct?
A. I'm not that familiar with all of the data on Namenda XR, but I have no reason to believe that the medication will be either less efficacious or more prone to side effects.
Q. All right. You have no basis to challenge the FDA's finding that Namenda XR is effective, correct?
A. That's right.
Q. Or safe, correct?
A. That's right.
Q. And both Namenda IR and Namenda XR are both -- both contain the same active pharmaceutical ingredient, memantine, correct?
A. That is correct.
Q. The concerns you expressed today, you never contacted my client, Forest, with any of those concerns, correct?
A. That's correct.

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Q. And the concerns you are expressing represent your own views as a doctor here today, correct?
A. That's correct.
Q. Other doctors may disagree with you, correct?
A. They may, yes.
Q. And you know of no published data regarding potential adverse effects that may result from switching patients from Namenda IR to Namenda XR, correct?
A. To the best of my knowledge, such studies haven't been done.
Q. And when we talk about adverse effects, that's the same as side effects; is that fair?
A. That's correct.
Q. OK. And you know of no --
A. I'm sorry. Let me clarify.
It may be either side effects, adverse effects in the form of side effects, or some other adverse effect on the patient because of a change in the effectiveness of a medication switching from one version to another.
Q. OK. So it may be slightly broader, the adverse effects, is that right?
A. Yes.
Q. OK. I'm just trying to get our terminology square.
Sir, you know of no clinical trial saying those switched from Namenda IR to XR might harm patients, correct?

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A. Yes. I believe I just said that.
Q. Let's talk about switching in the other direction, in other words, from Namenda XR to IR, which we sometimes have called a reverse commute in this case.
In that case, similarly, you know of no published data regarding potential adverse effects that may result from switching patients from Namenda XR to Namenda IR, correct?
A. That's correct.
Q. You know of no clinical trial saying that a switch from Namenda XR to IR might harm patients, correct?
A. That's correct.
Q. And you said you have -- when I deposed you earlier in this case, you said you had never read the Namenda XR label, correct?
A. The package insert label, that's correct.
Q. Right. The FDA-approved label for Namenda XR, correct?
A. That's correct.
Q. And today on direct you mentioned other sources of that information, right?
A. Yes.
Q. And you didn't mention those to me when I deposed you, correct?
A. I don't believe I did, no.
Q. And when you submitted your declaration that was referred to in this matter, you hadn't read the FDA-approved label for

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
----------x
THE PEOPLE OF THE STATE OF NEW YORK,

Plaintiff, New York, N.Y.

v. 14 Civ. 7473(RWS)

ACTAVIS, PLC, and FOREST LABORATORIES, LLC,

Defendants.
----------x

November 11, 2014
9:59 a.m.

Before:

HON. ROBERT W. SWEET,

District Judge

APPEARANCES

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PETER J. CARNEY
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JAIME M. CROWE

(Hearing resumed)

THE COURT: Thank you very much. Yes.

MR. GIDLEY: Your Honor, the next witness, as we understand it, that the State will call is the CEO of Actavis, Brent Saunders. Given that the testimony will be extensively relating to the future competitive plans of Actavis, we request that the courtroom be sealed for this testimony.

THE COURT: Hearing no objection, it will be.

MR. STOCK: Your Honor, I have a quick question about moving exhibits into evidence. Would you like us to do that all at the end or would you like us to do it on a day-by-day basis?

THE COURT: I wouldn't care dare tell experienced counsel what to do.

MR. STOCK: So if no one has an objection, we will move the exhibits that we introduced yesterday into evidence, and the defendant can could do the same.

THE COURT: Hearing no objection, they are admitted.

MR. PACE: Defendants likewise would move the admission of the exhibits that they used yesterday into evidence.

THE COURT: They are all admitted. You all will give the court reporter a list of the exhibits. That might help our record.

MR. GIDLEY: Will do, your Honor.

THE COURT: Where is our witness?

MR. STOCK: Mr. Saunders.

THE CLERK: Mr. Saunders.

THE WITNESS: Yes.

BRENTON SAUNDERS,
called as a witness by the plaintiff,
having been duly sworn, testified as follows:

THE CLERK: Please state your full name and spell your first name and last name for the record.

THE WITNESS: Brenton Saunders, B-r-e-n-t-o-n S-a-u-n-d-e-r-s.

THE CLERK: Thank you, Mr. Saunders. Please be seated.

THE WITNESS: Thank you.

DIRECT EXAMINATION

BY MR. STOCK:

Q. Good morning, Mr. Saunders.

A. Good morning.

Q. To just get us started, what I'd like to do in order to avoid having to repeatedly come up and give you an exhibit, we've put all the exhibits that we intend to use in a binder. So with the Court's permission, I am going to give a copy of the binder to the Court and to the witness.

THE COURT: Mm-hmm.

MR. STOCK: And there is an index which indicates the

plaintiff exhibit number for each of the documents that is in the binder.

BY MR. STOCK:

Q. Mr. Saunders, you are the CEO of Actavis, is that right?

A. That's correct.

Q. Am I pronouncing it correctly, Actavis?

A. You are.

Q. Actavis acquired Forest Laboratories in July 2014, isn't that right?

A. That's correct.

Q. AND prior to being the CEO of Actavis you were the CEO of Forest, is that right?

A. That is correct.

Q. And you took that position on or about October 1, 2013, is that correct?

A. On October 1, 2013.

Q. Thank you. Mr. Saunders, are you familiar with the term "patent cliff?"

A. I am. It is a term of art that has got a variety of different meanings.

Q. OK. Would you say that it refers to the dramatic decrease in sales of the brand with the dramatic rise of the generics at the time of loss of exclusivity?

A. I don't know. I probably would characterize it as the time when generic competitors come in and generally take 90 percent

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A. Well, I think you have to understand why this document was -- the context of this document, but it's hard for me to know if that seems right or not. Clearly, somebody was thoughtful enough to put it on this analysis.
Q. OK. Just to be clear what a soft switch is, a soft switch could be where you continue to distribute the old product but you put all your marketing resources solely behind the new product, right?
A. That could be the interpretation, yes.
Q. And so by these numbers, Forest was calculating, in January 2014, that as compared to doing a soft switch, a hard switch would generate [redacted] in additional sales of Namenda XR, right?
A. I think that was the point of view. You know, we'll see how competitive the marketplace is and what happens, but yes.
Q. Now, just to be totally clear about this document so there is no misunderstanding, I believe that some of the [redacted], just so the record is correct, some of the [redacted] -- so look on page 5, please.
So you see that second bullet from the bottom -- well, third bullet. The first bullet under the number says soft switch assumes IR loss of exclusivity in January and the hard switch includes pediatric exclusivity.
So just to be totally accurate here, some of that [redacted] on this presentation is not exclusively from the hard

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switch, it comes from the six months of additional pediatric exclusivity. Does that sound right to you?
A. That's what it looks like the document says.
Q. And so about [redacted] for Namenda is what, would you say?
A. [redacted]?
Q. Yes.
A. [redacted], or thereabouts.
Q. OK. So if that were true, then the hard-switch revenue would be about [redacted]; does that sound right?
A. It could be, yeah.
Q. OK. Now, Mr. Saunders, you understand that most states have what are known as generic substitution laws, right?
A. I am aware of that, yes.
Q. And you understand that under these laws, when generic Namenda IR enters the market, it can be substituted at the pharmacy for branded Namenda IR without the need to call a physician, right?
A. I think you said that backwards or I misheard you.
Q. I may have said it backwards.
Under the generic substitution laws, when generic Namenda IR enters the market, it can be substituted at the pharmacy for branded Namenda IR without the need to call a physician?
A. Yeah. The pharmacies can do a forced switch to generics.

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Q. You understand that for patients taking Namenda XR, Namenda IR generic cannot be dispensed by the pharmacy without contacting the physician's office, right?
A. That's correct and they will, yep.
Q. So for patients who move from Namenda IR to Namenda XR as a result of the forced switch, the generic substitution laws won't apply to them, right?
A. No, they won't force switch them. They'll try to persuade them to switch to the generic, though. They are financially motivated to.
Q. And that will require a call to the doctor's office, right?
A. Yeah, but they'll do a variety of other things as well.
Q. OK. And you know that once you've done the hard switch and converted patients over to Namenda XR, it's very difficult for generics to reverse-commute back for existing patients, right?
A. Well, in and of themselves there is, but they have lots of allies, so, you know, the biggest one being the pharmacies. So a patient walks in with an XR prescription and says, you know, I'd like to fill this prescription. The pharmacist will say $40 please, or if you would like, I can send your doctor a note and we can move you to IR and you can pay 5. That is the way it is going to work.
Q. But don't you agree that it is very difficult for generics to reverse-commute back for existing patients?
A. For generics -- the market isn't designed for generics as a

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standalone versus innovator. It is the innovator, the generic, the pharmacy, the PBM, the managed care company all working against the innovator. The decks are stacked incredibly the other way. That's why we refer to it as a dog fight.
Q. Let's take a quick look at that earnings -- January 21 earnings call again. Tab 8, page 19.
Are you still having trouble finding the page numbers?
A. Well, there are no page numbers. It is not a question of finding them.
Q. At the top of the page is, "Then we will fight for new RX's." It is about two pages from the back.
A. Yes, I found it.
Q. Again, this is from the January 21 investor call. You said, "Then we will fight for new RX's, and there we will be fighting with a better formulation, more convenient dozing as well as a combination product" -- I am reading the wrong part, sorry.
The next quote for Mr. Saunders: "Keep in mind that this is a behavioral change, so once -- if we do the hard switch and we've converted patients and caregivers to once-a-day therapy versus twice-a-day, it's very difficult for the generics, then, to reverse commute back, at least with the existing RX's. They don't have the sales force; they don't have the capabilities to do that. It doesn't mean that it can't happen. It just becomes very difficult, and it is an

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
----------x
THE PEOPLE OF THE STATE OF NEW YORK,

Plaintiff, New York, N.Y.

v. 14 Civ. 7473(RWS)

ACTAVIS, PLC, and FOREST LABORATORIES, LLC,

Defendants.
----------x

November 12, 2014
9:30 a.m.

Before:

HON. ROBERT W. SWEET,

District Judge

APPEARANCES

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THE DEPUTY CLERK: All rise.

THE COURT: Please be seated. Thank you very much. Schedule wise, we have motions at noon and so we'll break at noon and resume at 1:15, just so you all know what the schedule is.

Yes.

MR. GIDLEY: One quick housekeeping item, maybe two, your Honor.

MR. CARNEY: Your Honor, we just wanted to hand up to the Court hard copies of the transcript of Jason Harper from Mylan as it was played in court yesterday.

THE COURT: Good. Thank you.

MR. GIDLEY: And second one, your Honor, is we moved the admission of the following exhibits from the Saunders examination yesterday, that was DX-156, DX-158, DX-721, DX-811, DX-812.

THE COURT: Hearing no objection, they are admitted. Thank you.

(Defendant's Exhibits 156, 158, 721, 811 and 812 received in evidence)

MR. GIDLEY: Thank you, your Honor.

MR. STOCK: Your Honor, I have a similar motion, but I have to apologize. What I'd like to do is also move the admission of the Saunders exhibits that we provided, but I need to get you a list of those. Maybe I could just give them to

the Court Reporter just before the next break or something.

THE COURT: Okay, that's fine. But I think when you get the list, give it to counsel so we can see if there are any problems.

MR. STOCK: Yes. He has a list already. Thank you.

THE COURT: Thank you.

Yes. Professor, you're still under oath.

ERNST R. BERNDT,

called as a witness by the plaintiff,

having been previously sworn, testified as follows:

DIRECT EXAMINATION

BY MR. SIEGEL:

Q. Good morning, Professor Berndt.

A. Good morning.

Q. Okay, we're going to resume with the questioning now with when we left off we had finished talking about market definition issues. Do you recall that?

A. Yes, sir.

Q. Okay. I want to briefly turn to -- that was product market definition. I want to turn briefly to geographic market definition.

Have you arrived at a conclusion regarding what you believe is the relevant geographic market for antitrust purposes in this case?

A. Yes, sir, I have.

Q. And what is that?

A. It's the United States of America.

Q. Okay. And why have you come to that conclusion?

A. As I understand it, federal legislation prohibits the importation of prescription drugs other than for personal consumption. And so, for example, if Pfizer sold pharmaceuticals to distributors in Canada at a much lower price than they did to distributors in the U.S., distributors in Canada would not be permitted to import into the U.S. and essentially arbitrage.

And so the federal legislation, as I understand it, permits Pfizer to have a small and significant non-transitory price premium in the U.S. over elsewhere in the globe.

Q. Okay. So, in short, a drug company that is selling the drug into the United States with FDA approval and also into other countries in the world can successfully price discriminate between U.S. buyers, largely distributors and pharmacies and buyers outside of the United States; is that what you're saying?

A. Correct.

Q. Okay. Thank you. I want to -- you mentioned earlier that the hard switch, as we've defined it, would harm competition in the market for an NMDA antagonist. Do you recall giving that opinion?

A. Yes, sir.

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Q. Okay. Now, in your understanding with respect to -- can you just walk you us through what would happen in the case of the hard switch scenario occurred?
A. Yes. As I think I mentioned yesterday, I would interchangeably use the words hard switch and forced switch.
As I understand it, what a hard switch does is the following: Prior to the expiration of exclusivity on its Namenda IR product, a hard switch entails the manufacturer discontinuing selling that product in the United States, thereby forcing individuals who want to use that active pharmaceutical ingredient, namely, Memantine, forcing them to switch to Namenda XR extended release until a patent on or the exclusivity on the first generation product expires in July of next year.
For those individuals who want to have access to the lower cost generic IR post loss of exclusivity, they will need to switch again back to that formulation.
My understanding is that not all of those folks who were switched forcibly to extended release would switch back to the IR reason, IR formulation, in part because this is a population that's very vulnerable, and, as Dr. Lah pointed out, is quite resistant to change.
Q. And as a practical matter, what would be required to switch back from the XR to the IR generic once the IR generic becomes available?

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A. Because the XR on which they would be forcibly switched is not AB-rated to the IR formulation, they would need to obtain a new prescription.
Q. A new prescription from their physician?
A. Yes.
Q. And do you have a sense of roughly the number of generic Memantine IR sellers that are expected to enter upon loss of exclusivity in July 2015?
A. [redacted]
Q. Okay. In order to talk about the competitive harm that you found due to the forced switch, I want to ask you first, what would happen in this market, briefly, assuming there were no forced switch or hard switch, a generic launch happened occurred as expected, and let's say [redacted], what would happen to the market, the price and to sales?
A. If this were a conventional launch of a generic drug, the typical experience would be that upon expiration of the patent, there would be immediately some modest generic entry for upstream three, four, five entrants, perhaps two, depending on regulatory provisions. But very very quickly within three to

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six months more than 80 and perhaps as much as 90 or 95 percent of the branded prescriptions would have been switched to the AB-rated generic IR formulation, brought about largely through the automated switching that occurs at pharmacies when products are AB-rated to brand.
Q. And these are companies like Mylan, the company whose testimony we saw yesterday?
A. Correct.
Q. And --
A. May I finish?
Q. Yeah, sorry.
A. In terms of price, typically what happens is there's a modest price reduction within the first six months, but thereafter price drops precipitously. And typically it's not uncommon to find that the -- after six to nine months the price of the average price of the generic is ten to 20 percent of the price of the brand.
Q. So that if that's the typical case, what would happen in this case if in fact [redacted] entrants came in in July of 2015, what would happen to the price?
A. In this particular case what we need to assume is what is a proportion of those folks who are on -- forcibly put upon the XR medication, what proportion of them would now switch again, but this time to the generic IR formulation, and that is called the erosion rate. And that has been the subject of

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considerable research by folks at Forest, as well as at Mylan.
Q. Sorry, let me step back. I should clarify. I meant to ask in the non-forced switch scenario, [redacted], what happens in that case, the conventional non-hard switch scenario?
A. Within six months, 90 to 95 percent of the previous XR extended release consumers would be switched via the automated switching to AB-rated generic Memantine.
Q. Okay. Now let's turn to what I think you started to address a moment ago, which was what happens by contrast in the case of the forced switch, the forced switch does happen.
Can you just walk through what happens in that situation with respect to this particular case in terms of sales and price?
A. Yes. For those folks who between now and July 15th of next year are forcibly switched to the extended release version, because IR is withdrawn from the market essentially, they would now have the opportunity to switch again, but this time back to the immediate release formulation.
The proportion of users of XR who do that is called the erosion rate by analysts of this market, and there are various estimates of how large that erosion rate would be. Notice that if it were a conventional generic launch, as I said about 90 or 95 percent of those folks would switch to the generic.

they're almost certainly are none. I printed out the transcript of the earnings call.

Q. Now, what does -- you mentioned William Meury was a senior marketing person at this earnings call. What, if anything, does he say regarding the erosion rate? And I turn your attention to page 15 of 21 in the original version or 25 of 30 in the more clearly printed version?

A. I have it.

Q. Okay. And this is I believe in response to a question by Elliott Wilbur of Needham and Company. He asks the question of Brent Saunders and William Meury. And I see William -- Brent Saunders turns over the microphone to William Meury.

Maybe you could just read the Brent Saunders William Meury colloquy real quick, just the short paragraphs in?

A. Yes. Brent Saunders says, "I'll turn it over to Bill in a second. I think in terms of generic IR, we do get the pediatric extension as we expect. The generic should enter the market around July of 2015 as the date of the settlement date, so it's pretty much set in stone. I think you want to talk a little bit about the conversion and the leakage rate?" And William Meury responds, "Yeah. If you look at the XR formulations that face generic alternatives, there is a fairly wide range of erosion. It can could be as low as you point out in the 5 percent to 10 percent range. It could climb to 30 percent or more. And what I would keep in mind with Namenda

XR is that it is a relatively fragile population of patients. We think that the dosing schedule here is particularly relevant, and that we should preserve a good portion of our Namenda" -- it has sells, I believe it's a typo meaning sales, but that's my own inference. "Now I don't think we'll be at the lower end of the range necessarily, but I don't think that we'll exceed the high end of the range either."

Q. Okay. Now what did you take way from this exchange?

A. I take it that by April of this year, Forest had conducted a fair bit of research, its marketing folks had done that; that they came up with a wide range of estimates, and that Mr. Meury and Mr. Saunders believed the range of five to 30 percent is a reasonable range.

But notably it's much much less than 100 percent or the 90 percent you would get from a conventional launch.

Q. And did you consider this to be, or I should say do you consider this to be a credible source of information?

A. Yes, for several reasons. One is they've been working on this research for more than a year starting in 2012, and Mr. Meury is senior manager, and this is a public meeting to shareholders in which it's required that material information be disclosed.

Q. Is this the most recent documented evidence that you've seen from Forest of the erosion rate?

A. Yes. And I believe Mr. Saunders reiterated that erosion

rate in his testimony yesterday. I think he said 30 percent.

Q. Okay. And this estimate was given in April of this year?

A. Correct.

Q. And what do you think of this estimate, given the other documents and data you've seen?

A. [redacted]. And based on my own research and my understanding of this population, I would think it's probably in that five to 30 percent range. Because remember these folks are not your robust 50-year-old population. They're very fragile, vulnerable population. And when given the chance to vote with their feet over the 13 months, a minority of them actually switched voluntarily.

Q. And do you believe that's why Mr. Meury mentioned in the Wall Street earnings call that this is -- keep in mind that this, with Namenda XR that it is a relatively fragile population of patients, in response to a question about erosion rate?

MR. GIDLEY: Objection, foundation.

THE COURT: Sustained.

Q. Did you take any -- were you able to take any information

or make any inferences from the -- or how did you understand the mention of relatively fragile population in Mr. Meury's answer?

A. I think there are two competing hypotheses about that. One is that I think Mr. Meury's is hinting that a dosing schedule of once a day would be particularly valuable to this population.

I think the counter hypotheses is that they're resistant to change. And while it might be more convenient, the cost of psychic and otherwise of change is high.

And I think the evidence, to date, in terms of market share when the two products were on the market simultaneously that a minority of patients switched, tells me that it's the latter hypotheses that has greater evidence and support.

Q. Okay. I'd like to turn to the Berndt declaration tab one, back to tab one at figure five?

A. On what page, sir?

Q. Figure five is on page 40. This actually relates to Mylan again. I don't know if --

MR. GIDLEY: I don't see anyone from our client here.

MR. SIEGEL: Okay.

Q. Okay. [redacted]

A. [redacted]

EXHIBIT

521

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE NAMENDA DIRECT PURCHASER **ANTITRUST LITIGATION**	**No. 15-cv-7488-CM** **FILED UNDER SEAL**

FOREST'S RESPONSES TO DIRECT PURCHASER PLAINTIFFS' STATEMENT OF MATERIAL FACTS ON COUNT THREE AND COUNTER-STATEMENT OF MATERIAL FACTS NOT IN DISPUTE

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Pursuant to Rule 56.1 of the Local Rules of the United States District Court for the Southern District of New York, Forest Laboratories LLC and Actavis, plc ("Forest") and Merz GmbH & Co. KGaA, Merz Pharmaceuticals GmbH, and Merz Pharma GmbH & Co. KGaA ("Merz") (collectively, "Defendants") hereby submit (1) responses to the Direct Purchaser Class Plaintiffs' ("Plaintiffs" or "DPPs") Statement of Material Facts in Support of their Motion for Partial Summary Judgment on Count Three ("Plaintiffs' Statement"), as well as (2) additional undisputed facts supporting Forest's Opposition to Plaintiffs' Motion for Summary Judgment on Count Three and Forest's Motion for Summary Judgment on Count Three.

MERZ'S GENERAL OBJECTIONS TO DPPS' LOCAL RULE 56.1 STATEMENT

DPPs' Motion is directed to Count Three, which is alleged only against Forest. For the purposes of these Responses, it is assumed that "Defendants" refers only to Forest Laboratories LLC and Actavis plc. To the extent that the Statement defines "Defendants" to include Merz GmbH & Co. KGaA, Merz Pharma GmbH & Co. KGaA, and Merz Pharmaceuticals GmbH ("Merz"), Defendants object to improperly including a party against whom the claim that is the subject of the Motion is not made. Defendants specifically incorporate this objection into each and every response below.

FOREST'S GENERAL OBJECTION TO DPPS' LOCAL RULE 56.1 STATEMENT

Forest objects to Plaintiffs' Statement to the extent it is premised on Judge Sweet's 2014 opinion in *People of the State of New York v. Actavis*, Civil Action No. 14-cv-7473 (S.D.N.Y.) and the Second Circuit's opinion affirming the preliminary injunction in *New York v. Actavis, plc.*, No. 14-4624 (2d Cir.) (collectively "NYAG Action"). As explained in Forest's Opposition to DPPs' Motion for Summary Judgment and Collateral Estoppel on Count One, the issues addressed and evidence presented in the NYAG action are significantly different from those in this case, and therefore the NYAG Action opinions do not constitute binding evidentiary findings

as to any factual issue in this case. Forest further objects to Plaintiffs' Statement to the extent it is premised on legal conclusions rather than facts.

FORESTS RESPONSES TO
DPPs' LOCAL RULE 56.1 STATEMENT OF FACTS

In the sections below, Forest reproduces Plaintiffs' Statement verbatim, including Plaintiffs' footnotes, with Forest's responses interposed below the text of each of Plaintiffs' statements.

Forest's responses are based on the limited discovery record available to Forest at this time, and are made solely in the context of this motion for partial summary judgment. Evidence cited by Forest in support of or in contradiction of a particular proposition should not be construed as the only evidence supporting or contradicting the proposition in question, and Forest specifically reserves the right to provide additional evidence as is necessary and appropriate. Additionally, the phrases "do not dispute," "undisputed," and "not disputed" as used herein shall not be construed as a concession by Forest that a statement is (a) material, (b) complete, (c) supported by the documents or exhibits cited, (d) admissible at trial, or (e) otherwise relevant. Where Forest does not dispute the facts in a particular paragraph, it does so for the purposes of DPPs' motion for partial summary judgment only, and Forest reserves all other objections, including, but not limited to, the right to object to or contest each of DPPs' assertions of fact at the appropriate time, including the right to challenge each assertion of fact as to admissibility at trial. Forest reserves all rights with respect to these assertions, including the right to supplement its responses herein.

I. Forest

A. Namenda IR & the '703 Patent

1. Forest, now Allergan,[1] markets memantine hydrochloride in the United States as "Namenda."[2]

Response: Not disputed, but for clarity, Forest adds that it also markets memantine hydrochloride under the trade name "Namenda XR." *See* Namenda XR® Label, Adam Ex. 1.

2. The FDA has approved Namenda for use in patients with moderate and severe Alzheimer's disease.[3]

Response: Not disputed, although the judicial opinion that Plaintiffs cite is not factual evidence. See supra Forest's General Objection.

3. On or about June 2000, Forest and Merz,[4] a German company, entered into a license and cooperation agreement for the development of memantine hydrochloride to be used for Alzheimer's disease.[5]

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[1] The term "Forest" refers to Forest Laboratories, LLC, which was subsequently acquired by Allergan plc (formerly Actavis, plc.).

[2] Complaint, *Forest Laboratories, Inc., et al. v. Dr. Reddy's Laboratories, Inc., et al*., Case No. 08-052 (D. De.) (ECF No. 1, filed Jan. 25, 2008) (hereinafter "'052 Complaint"), attached as Exhibit 1 to the Declaration of Dan Litvin (hereinafter "Litvin Declaration"), at ¶ 33 (alleging "Forest is the exclusive distributor of Namenda® in United States."). *See also* Memorandum in Support of Defendants Forest and Merz's Motion to Dismiss Indirect Purchaser Plaintiffs' Class Action Complaint and Direct Purchaser Plaintiffs' First Amended Class Action Complaint, ECF No. 57 (filed 12/22/2015) (hereinafter "Defendants' MTD Brief"), at 6, n. 6 ("Memantine is a N-Methy-D-Aspartate receptor antagonist, which works to prevent the overstimulation of glutamate, an amino acid which can cause toxicity to neurons in the brain.").

[3] *N.Y. ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 647 (2d Cir.), *cert. dismissed sub nom. Allergan PLC v. N.Y. ex. rel. Schneiderman*, 136 S. Ct. 581, 193 L. Ed. 2d 421 (2015) ("Namenda IR was the first medication approved for individuals suffering from moderate-to-severe Alzheimer's disease.").

[4] The term "Merz" refers to Merz GMBH & Co. KGAA, Merz Pharma GMBH & Co. KGAA, Merz Pharmaceuticals GMBH, and/or Merz + Co. GmbH & Co.

[5] Merz-Forest Supply and Cooperation Agreement, dated June 28, 2000, (FRX-AT-01710620 - FRX-AT-01710663), attached as Exhibit 2 to the Litvin Declaration. *See also N.Y. v. Actavis, PLC*, No. 14-cv-7473, 2014 WL 7015198, at *10 (S.D.N.Y. Dec. 11, 2014) (hereinafter "*Namenda I*"), *aff'd sub nom. N.Y. ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir.

Response: Not disputed, although the judicial opinions that Plaintiffs cite are not evidence. See supra Forest's General Objection.

4. As part of that agreement, Forest obtained exclusive rights to market a memantine hydrochloride product in the United States under Merz's 5,061,703 patent (the "'703 patent").[6]

Response: Not disputed, although the judicial opinion that Plaintiffs cite is not evidence. See supra Forest's General Objection.

5. In December 2002, Forest submitted NDA No. 21-487 to the FDA, seeking approval to market memantine hydrochloride tablets (5mg and 10mg) – branded as Namenda – for the treatment of Alzheimer's.[7]

Response: Not disputed, although the judicial opinion that Plaintiffs cite is not evidence. See supra Forest's General Objection.

6. Forest's NDA was approved on October 16, 2003 for Namenda immediate release (IR) tablets.[8]

2015) ("In June 2000, Forest obtained an exclusive license to U.S. Patent No. 5,061,703 held by Germany's Merz Pharma GmbH & Co. KGaA . . . .").

[6] *Namenda I*, at *10 ("In June 2000, Forest obtained an exclusive license to U.S. Patent No. 5,061,703 held by Germany's Merz Pharma GmbH & Co. KGaA,"); '052 Complaint, at ¶ 32 (alleging "Forest is the exclusive licensee of the '703 patent in the United States"), ¶ 33 (alleging "Forest is the exclusive distributor of Namenda® in United States."). *See also* Settlement agreement with Amneal, dated Sept. 1, 2009, FRX-AT-00000218 - FRX-AT-00000252, attached as Exhibit 3 to the Litvin Declaration (hereinafter "Amneal Settlement") at Ex. B (License Agreement)

[7] *Namenda I*, at *10 ("In December 2002, Forest submitted an NDA to the FDA, seeking approval to market memantine HCL tablets (5mg and 10mg) branded as 'Namenda' for the treatment of Alzheimer's. U.S. Food & Drug Admin., NDA 21–487 Approval Letter (DX782) (Oct. 16, 2003)."). *See also* '052 Complaint, at ¶ 32 (alleging "Forest holds New Drug Application ('NDA') No. 21-487 for Namenda® brand memantine hydrochloride tablets.").

[8] *Id.* ("On October 16, 2003, the FDA approved Namenda Instant Release Tablets ('Namenda' or 'Namenda IR') for the treatment of moderate-to-severe Alzheimer's disease. FDA Approval Letter, Application No. 21–487 from Robert Temple, Dir., Office of Drug

Response: Forest does not dispute that the FDA approved Namenda immediate release tablets on October 16, 2003, as described in the FDA approval letter that Plaintiffs cite in their paragraph 6/footnote 8. Forest notes that the judicial opinion that Plaintiffs cite is not evidence. See supra Forest's General Objection.

7. In January 2004, Forest commercially launched Namenda IR tablets in the United States.[9]

Response: Not disputed, although the judicial opinion that Plaintiffs cite is not evidence. See supra Forest's General Objection.

8. In conjunction with obtaining regulatory approval of Namenda, the '703 patent was listed in the FDA's "Orange Book" as covering Namenda.[10]

Response: Not disputed.

9. The '703 patent, which was obtained in 1991, was originally set to expire on April 11, 2010.[11]

Response: Not disputed, but for clarity, Forest responds that that the '703 patent issued from the PTO on October 29, 1991 and had an expiration date of April 11, 2015 pursuant to 35 U.S.C. § 156.

Evaluation I, Ctr. for Drug Evaluation & Research, to Doreen V. Morgan, Forest Labs., Inc. (PX10) (Oct. 16, 2003).").

[9] *Id.* ("Forest brought Namenda IR to market in January of 2004. Press Release, Forest Labs., Inc., Namenda(TM) (memantine HCl), First Drug Approved For Treatment of Moderate to Severe Alzheimer's Disease Now Available Nationwide (PX11) (Jan. 13, 2004).").

[10] '052 Complaint, at ¶ 32 ("The '703 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ('Orange Book') for Namenda.®"). *See also* FDA Final Approval Letter Concerning Dr. Reddy's ANDA No. 090048, dated April 14, 2010, attached as Exhibit 4 to the Litvin Declaration (acknowledging that the Namenda was subject to the '703 patent).

[11] Forest's Answer, ECF No. 107 (filed Sept. 27, 2016), at 19 ("Forest . . . admits that the '703 patent issued in 1991. . . . Forest admits the PTO granted Forest an extension under 25 U.S.C. § 156 extending the term of the '703 patent for a 5 year period from April 11, 2010.").

10. Forest submitted an application to the Patent and Trademark Office (the "PTO") seeking a five-year patent extension.[12]

Response: Not disputed.

11. In March 2009, the PTO granted Forest the five-year extension.[13]

Response: Not disputed.

12. As a result, the term of the '703 patent was extended, from its original expiration date, to April 11, 2015.[14]

Response: Not disputed, although the judicial opinion that Plaintiffs cite is not evidence. See supra Forest's General Objection.

B. Pediatric Exclusivity

13. In January 2014, Forest sought six months of pediatric exclusivity for Namenda IR tablets from FDA.[15]

Response: Disputed. The hyperlink Plaintiffs offer as proof that "Forest sought six months of pediatric exclusivity" in "January 2014" does not support those facts. Rather, the hyperlink simply indicates that the "Date of Exclusivity" for memantine is June 16, 2014. Furthermore, the pediatric exclusivity statute authorizes an award of exclusivity only if the FDA requests that a New Drug Applicant perform pediatric studies and those studies are performed to the FDA's

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[12] USPTO Notice of Final Determination, dated March 3, 2009, attached as Exhibit 5 to the Litvin Declaration.

[13] *Id*. (providing that the USPTO has granted a five-year extension on the term of the '703 patent).

[14] *Namenda I*, at *10 ("Forest's main patent for Namenda IR, the '703 patent, expires on April 11, 2015. U.S. Patent and Trademark Office, Patent Term Extensions (PX12)."). *See also* FDA Final Approval Letter Concerning Dr. Reddy's ANDA No. 090048, dated April 14, 2010 (acknowledging that the Namenda was subject to the '703 patent, which was scheduled to expire on April 11, 2015).

[15] FDA Pediatric Exclusivity Determinations identifies June 16, 2014 as the "Date of Exclusivity" for the drug "Memantine" as sponsored by "Forest Labs" (available at http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DevelopmentResources/UCM514985.pdf).

satisfaction. Forest acknowledges that the "FDA encourages applications to make" proposals for pediatric studies. FDA, Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act: Frequently Asked Questions on Pediatric Exclusivity (505A), available at https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm077915.htm, Question 2 (Last Updated Nov. 30, 2016), Adam Ex. 2. Such a proposal, however, is not a guarantee that the FDA will issue a written request for pediatric studies. Id. (After receiving a proposal, the "FDA will review the submitted proposal and MAY issue a Written Request.") Whether a written request issues is entirely within the FDA's discretion. See id. Nonetheless, Forest does not dispute that it conducted pediatric studies at the FDA's request and was ultimately awarded pediatric exclusivity for conducting those studies. See Letter from Robert Temple (FDA) to Kathleen Waldron (Forest Labs., Inc., Associate Director) (Jan. 25, 2012), Adam Ex. 3.

14. This request was based on studies regarding the use of memantine hydrochloride in pediatric patients with autism.[16]

Response: Disputed to the extent Plaintiffs suggest that Forest's "request" resulted in pediatric exclusivity. See supra Response to Paragraph 13. Further disputed in that the judicial opinion that Plaintiffs cite is not evidence. See supra Forest's General Objection. However, Forest does not dispute that it "conduct[ed] costly pediatric studies for the treatment of autistic children," as stated in the brief that Plaintiffs cite in paragraph 14/footnote 16.

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[16] Memorandum in Support of Defendants Forest and Merz's Motion to Dismiss Indirect Purchaser Plaintiffs' Class Action Complaint and Direct Purchaser Plaintiffs' First Amended Class Action Complaint, ECF No. 57 (filed 12/22/2015) (hereinafter "Defendants' MTD Brief"), p. 50 ("Forest earned six additional months of regulatory exclusivity by conducting costly pediatric studies for the treatment of autistic children, at the FDA's request."). *See also Namenda I*, at *11 ("In 2009, Forest began a large program to evaluate whether memantine could be approved to treat pediatric autism at the FDA's 'official request,' known as a 'Pediatric Written Request' ('PWR').").

15. In June 2014, FDA granted Forest's request for six months of pediatric exclusivity.[17]

Response: Disputed to the extent Plaintiffs suggest that Forest's "request" resulted in pediatric exclusivity. See supra Response to Paragraph 13. Forest does not dispute that it obtained six months of pediatric exclusivity but notes that the judicial opinion that Plaintiffs cite is not evidence. See supra Forest's General Objection.

II. The Generic Companies

16. Hereinafter, the term "7 Generic Companies" refers to Interpharm Holdings, Inc. and Interpharm, Inc. (together, "Interpharm") (whose interests were acquired by a wholly owned subsidiary of Amneal Pharmaceuticals, LLC) (hereinafter referred to collectively as "Amneal"); Dr. Reddy's Laboratories Ltd. and/or Dr. Reddy's Laboratories, Inc. (together, "Dr. Reddy's"); Lupin Pharmaceuticals, Inc. ("Lupin"); Mylan Pharmaceuticals, Inc. ("Mylan"); Orchid Chemicals & Pharmaceuticals Ltd. ("Orchid"); Sun India Pharmaceuticals Industries, Ltd. ("Sun"); and Teva Pharmaceuticals USA, Inc. ("Teva").

Response: Not disputed.

A. Amneal

17. Amneal submitted its ANDA on or about October 16, 2007.[18]

Response: Not disputed.

18. Amneal filed a Paragraph IV certification with its ANDA.[19]

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[17] Defendants' MTD Brief, p. 50 ("Forest earned six additional months of regulatory exclusivity by conducting costly pediatric studies for the treatment of autistic children, at the FDA's request."); *Namenda I*, at *11 ("On June 18, 2014, Forest announced that FDA had granted its request for pediatric exclusivity, extending Forest's exclusivity rights for another six months. Press Release, Forest Labs., Inc., Forest Obtains Six Months U.S. Pediatric Exclusivity for Namenda R and Namenda XR (PX13) (June 18, 2014).").

[18] FDA Final Approval Letter Concerning Amneal's ANDA No. 090041, dated April 10, 2015, attached as Exhibit 6 to the Litvin Declaration. ("This is in reference to your abbreviated new drug application (ANDA) received on October 16, 2007, and submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Memantine Hydrochloride Tablets USP, 5 mg and 10 mg.").

[19] '052 Complaint, at ¶ 52 (alleging that the ANDA of Interpharm (now Amneal) contained a Paragraph IV certification).

Response: Not disputed.

19. Interpharm (now Amneal) sent its Paragraph IV notice to Forest and Merz on December 19, 2007.[20]

Response: Not disputed.

20. This Paragraph IV certification provided that the '703 patent was invalid and/or not infringed by Amneal's products.[21]

Response: Disputed that Amneal's Paragraph IV notice "provided" for invalidity or non-infringement of the '703 patent. Rather, Amneal's Paragraph IV notice alleged that the '703 patent was invalid or that Amneal's proposed generic product would not infringe the '703 patent. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (An ANDA shall contain "a certification, in the opinion of the applicant and to the best of his knowledge, . . . that such patent is invalid or will not be infringed") (emphasis added).

21. On January 25, 2008, Forest and Merz filed a Hatch-Waxman lawsuit in the United States District Court for the District of Delaware against Interpharm (now Amneal) (as well as co-defendants, Dr. Reddy's, Mylan, and Sun) alleging infringement of the '703 patent.[22] This became Case No. 08-cv-00052 (D. Del.).[23]

Response: Not disputed.

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[20] '052 Complaint, at ¶ 52.

[21] FDA Final Approval Letter Concerning Amneal's ANDA No. 090041, dated April 10, 2015 ("Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '703 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Memantine Hydrochloride Tablets USP, 5 mg and 10 mg, under this ANDA.").

[22] '052 Complaint, at ¶ 51-58.

[23] *Id.*

22. On June 2, 2008, the lawsuit against Amneal was consolidated into case No. 08-cv-00021 (a similar Hatch –Waxman lawsuit against Lupin, Orchid, Teva, and others), with the '021 case becoming the lead case.[24]

Response: Not disputed.

23. In September 2009, Forest and Merz settled with Amneal.[25]

Response: Not disputed.

24. In connection with this settlement, Amneal agreed, among other things, to discontinue its efforts to challenge the '703 patent.[26]

Response: Disputed as incomplete and misleading. The settlement between Forest and Amneal provided

. See Amneal Settlement Agreement, at § 5, Litvin Ex. 3. The parties also agreed

. See id, Exhibit B (License Agreement), at §§ 1.14, 2.1, 3.2.

25. Also in connection with this settlement, Amneal agreed to not launch its generic product until the exact same day, on January 11, 2015, that the other 6 of the 7 Generic Companies agreed to launch.[27]

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[24] Order of Consolidation, *Forest Laboratories, Inc., et al. v. Cobalt Laboratories Inc., et al.*, 08-cv-00021 (D. Del.) (ECF No. 76, filed June 2, 2008), attached as Exhibit 7 to the Litvin Declaration.

[25] *See* Amneal Settlement.

[26] *Id*. at p. 2 (FRX-AT00000219)

See also Defendants' MTD Brief, p. 9 ("The first generic to settle was Amneal Pharmaceuticals LLC ('Amneal'), on September 1, 2009. . . . As a part of this settlement, Amneal released its claim that the '703 patent was invalid, unenforceable, or not infringed.").

Response: Forest disputes that its settlement with Amneal was an "agree[ment] to not launch" Amneal's proposed generic product. Consistent with the U.S. patent laws and the Hatch-Waxman Act, Forest sued Amneal under 35 U.S.C. § 271(e) alleging infringement of the presumptively valid '703 patent. Pursuant to the parties' settlement of that litigation, Forest granted Amneal a license to the '703 patent, enabling Amneal to begin selling its product (1) three months before the '703 patent was to expire, or, (2) if Forest obtained pediatric exclusivity, three months before that exclusivity was to expire. See Amneal Settlement Agreement, at § 2, Litvin Ex. 3; Id., Exhibit B, (License Agreement), at §§ 1.14, 2.1, 3.2.

26. This agreement, along with the agreements of the other 6 of the 7 Generic Companies, contained a provision that extended the agreed-upon generic launch date from January 11, 2015 to July 11, 2015 in the event that, subsequent to the

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[27] *Id.*, at Ex. B (License Agreement) (FRX-AT-00000236 - FRX-AT-00000240) ("1.14 'Launch Date' shall mean the later of: (a) 3 calendar months prior to the expiration of the '703 Patent, including any extensions and/or pediatric exclusivity, whether granted before, on or after the Execution Date; or (b) the date that Amneal obtains final approval from the FDA of the Amneal ANDA, unless accelerated as described herein. . . .

consummation of the execution of these agreements, Forest was granted an additional six-month pediatric exclusivity period for Namenda.[28]

Response: Not disputed.

27. Amneal, along with the other 6 of the 7 Generic Companies, maintained its Paragraph IV certification to the '703 Patent.[29]

Response: Forest does not dispute Plaintiffs' quotation of the FDA approval letter for Amneal's ANDA No. 090041 (in footnote 29), but clarifies that Amneal's ANDA did not contain a Paragraph IV certification after the '703 patent expired. See 21 U.S.C. § 355a(c)(1)(B)(i)(I); see also Mylan Labs., Inc. v. Thompson, 389 F.3d 1272, 1278 (D.C. Cir. 2004) ("when [NDA holder]'s patent expired [generic company]'s paragraph IV certification would no longer be accurate and [generic company] would be required to amend it, or . . . FDA can treat that certification as automatically amended to contain a paragraph II certification[.]").

28. The FDA granted final approval of Amneal's ANDA on April 10, 2015.[30]

Response: Forest does not dispute that the FDA sent Amneal a letter on April 10, 2015 stating that "the [Amneal] ANDA is approved" but disputes that the approval is properly considered "final," as explained in Forest's Brief, in Section III(C)(3).

29. The FDA never rescinded Amneal's final approval.[31]

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[28] *Id*.

[29] FDA Final Approval Letter Concerning Amneal's ANDA No. 090041, dated April 10, 2015 ("Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '703 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Memantine Hydrochloride Tablets USP, 5 mg and 10 mg, under this ANDA.").

[30] FDA Final Approval Letter Concerning Amneal's ANDA No. 090041, dated April 10, 2015 ("the ANDA is approved").

[31] Current FDA Electronic Orange Book, Product Details for Amneal's ANDA No. 090041 (providing that FDA approved Amneal's ANDA No. 090041 on April 10. 2015) (available at

Response: Disputed. The current version of the FDA's electronic Orange Book is not evidence that the FDA never rescinded or otherwise adjusted the approval it granted Amneal on April 10, 2015. Forest further disputes that the approval of Amneal's ANDA granted on April 10, 2015 is properly considered "final," as explained in Forest's Brief, in Section III(C)(3).

30. By July 11, 2015, Amneal began commercially marketing immediate release Namenda tablets in the U.S.[32]

Response: Disputed. Plaintiffs have not proven that the cited website confirms the date as of which Amneal began selling its generic version of Namenda or that the website itself is admissible evidence and therefore appropriate for consideration under FRCP 56(c)(2) ("A party may object that the material cited to support or dispute a fact cannot be presented in a form that would be admissible in evidence.").

B. Dr. Reddy's

31. Dr. Reddy's submitted its ANDA on October 16, 2007.[33]

Response: Not disputed.

32. Dr. Reddy's filed a Paragraph IV certification with its ANDA.[34]

Response: Not disputed.

33. Dr. Reddy's sent its Paragraph IV notice to Forest and Merz on January 4, 2008.[35]

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http://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=090041#).

[32] FDA National Drug Code Directory (available at http://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm) identifies April 30, 2015 as the "Start Marketing Date" for "Amneal Pharmaceuticals of New York LLC's" ANDA No. 090041.

[33] FDA Final Approval Letter Concerning Dr. Reddy's ANDA No. 090048, dated April 14, 2010 (acknowledging that Dr. Reddy's submitted its ANDA on October 16, 2007).

[34] '052 Complaint, at ¶ 37 (alleging that Dr. Reddy's ANDA contained a Paragraph IV certification).

[35] *Id*. at ¶ 36.

Response: Not disputed.

34. This Paragraph IV certification provided that the '703 patent was invalid and/or not infringed by Dr. Reddy's products.[36]

Response: Disputed that Dr. Reddy's Paragraph IV notice "provided" for invalidity or non-infringement of the '703 patent. Rather, Dr. Reddy's Paragraph IV notice alleged that the '703 patent was invalid or that Dr. Reddy's proposed generic product would not infringe the '703 patent.

35. On January 25, 2008, Forest and Merz filed a Hatch-Waxman lawsuit in the United States District Court for the District of Delaware against Dr. Reddy's (as well as co-defendants Interpharm (now Amneal), Mylan, and Sun) alleging infringement of the '703 patent.[37] This became Case No. 08-cv-00052 (D. Del.).[38]

Response: Not disputed.

36. On June 2, 2008, the lawsuit against Dr. Reddy's was consolidated into case No. 08-cv-00021 (a similar Hatch –Waxman lawsuit against Lupin, Orchid, Teva, and others), with the '021 case becoming the lead case.[39]

Response: Not disputed.

37. In November 2009, Forest and Merz settled with Dr. Reddy's.[40]

Response: Not disputed.

38. In connection with this settlement, Dr. Reddy's agreed, among other things, to discontinue its efforts to challenge the '703 patent.[41]

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[36] *Id*.

[37] *Id*. at ¶ 35-42.

[38] *Id*.

[39] Order of Consolidation, *Forest Laboratories, Inc., et al. v. Cobalt Laboratories Inc., et al.*, 08-cv-00021 (D. Del.) (ECF No. 76, filed June 2, 2008).

[40] Settlement Agreement with Dr. Reddy's, dated Nov. 13, 2009, FRX-AT-00000001 - FRX-AT-00000037, attached as Exhibit 8 to the Litvin Declaration (hereinafter "Dr. Reddy's Settlement").

Response: Disputed as incomplete and misleading. The settlement between Forest and Dr. Reddy's provided

See Dr. Reddy's Settlement Agreement, at § 6, Litvin Ex. 8. The parties also agreed

. See id., Exhibit B (License Agreement), at §§ 1.16, 2.1, 3.2.

39. Also in connection with this settlement, Dr. Reddy's agreed to not launch its generic product until the exact same day, on January 11, 2015, that the other 6 of the 7 Generic Companies agreed to launch.[42]

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[41] *Id*. at 2 (FRX-AT-00000002)

[42] *Id*. at Ex. B (License Agreement) (FRX-AT-00000019, FRX-AT-00000021, FRX-AT-00000023-24) ("1.16 'Launch Date' shall mean the later of: (a) 3 calendar months prior to the expiration of the '703 Patent, including any extensions and/or pediatric exclusivity, whether granted before, on or after the Execution Date; or (b) the date that DRL obtains final approval from the FDA of the DRL ANDA, unless accelerated as described herein. . . .

Response: Forest disputes that its settlement with Dr. Reddy's was an "agree[ment] to not launch" Dr. Reddy's proposed generic product. Consistent with the U.S. patent laws and the Hatch-Waxman Act, Forest sued Dr. Reddy's under 35 U.S.C. § 271(e) alleging infringement of the presumptively valid '703 patent. Pursuant to the parties' settlement of that litigation, Forest granted Dr. Reddy's a license to the '703 patent, enabling Dr. Reddy's to begin selling its product

. See Dr. Reddy's Settlement Agreement, at § 2, Litvin Ex. 8; Id., Exhibit B (License Agreement), at §§ 1.16, 2.1, 3.2.

40. This agreement, along with the agreements of the other 6 of the 7 Generic Companies, contained a provision that extended the agreed-upon generic launch date from January 11, 2015 to July 11, 2015 in the event that, subsequent to the consummation of the execution of these agreements, Forest was granted an additional six-month pediatric exclusivity period for Namenda.[43]

Response: Not disputed.

41. Dr. Reddy's, along with the other 6 of the 7 Generic Companies, maintained its Paragraph IV certification to the '703 Patent.[44]

Response: Forest does not dispute Plaintiffs' quotation of the FDA approval letter for Dr. Reddy's ANDA No. 090048 (in footnote 44), but clarifies that Dr. Reddy's ANDA did not

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[43] *Id.*

[44] FDA Final Approval Letter Concerning Dr. Reddy's ANDA No. 090048, dated April 14, 2010 ("Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '703 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Memantine Hydrochloride Tablets USP, 5 mg and 10 mg, under this ANDA.").

contain a Paragraph IV certification after the '703 patent expired. See 21 U.S.C. § 355a(c)(1)(B)(i)(I); see also Mylan Labs., 389 F.3d at 1278 ("when [NDA holder]'s patent expired [generic company]'s paragraph IV certification would no longer be accurate and [generic company] would be required to amend it, or . . . FDA can treat that certification as automatically amended to contain a paragraph II certification[.]").

42. The FDA granted final approval of Dr. Reddy's ANDA on April 14, 2010.[45]

Response: Forest does not dispute that the FDA sent Dr. Reddy's a letter on April 14, 2015 stating that "the [Dr. Reddy's] ANDA is approved" but disputes that the approval is properly considered "final," as explained in Forest's Brief, in Section III(C)(3).

43. The FDA never rescinded Dr. Reddy's final approval.[46]

Response: Disputed. The current version of the FDA's electronic Orange Book is not evidence that the FDA never rescinded or otherwise adjusted the approval it granted Dr. Reddy's on April 14, 2015. Forest further disputes that the approval of Dr. Reddy's ANDA granted on April 14, 2015 is properly considered "final," as explained in Forest's Brief, in Section III(C)(3).

44. By July 11, 2015, Dr. Reddy's began commercially marketing immediate release Namenda tablets in the U.S.[47]

Response: Disputed. Plaintiffs have not proven that the cited website confirms the date as of which Dr. Reddy's began selling its generic version of Namenda or that the website itself is

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[45] *Id.*

[46] Current FDA Electronic Orange Book, Product Details for Dr. Reddy's ANDA No. 090048 (providing that the FDA approved Dr. Reddy's ANDA on April 14, 2010) (available at http://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=090048#).

[47] FDA National Drug Code Directory, available at http://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm, identifies July 11, 2015 as the "Start Marketing Date" for "Dr. Reddy's Laboratories Limited" ANDA No. 090048.

admissible evidence and therefore appropriate for consideration under FRCP 56(c)(2) ("A party may object that the material cited to support or dispute a fact cannot be presented in a form that would be admissible in evidence.").

C. Lupin

45. Lupin submitted its ANDA on October 16, 2007.[48]

Response: Not disputed.

46. Lupin filed a Paragraph IV certification with its ANDA.[49]

Response: Not disputed.

47. Lupin sent its Paragraph IV notice to Forest and Merz on December 14, 2007.[50]

Response: Not disputed.

48. This Paragraph IV certification provided that the '703 patent was invalid and/or not infringed by Lupin's products.[51]

Response: Disputed that Lupin's Paragraph IV notice "provided" for invalidity or non-infringement of the '703 patent. Rather, Lupin's Paragraph IV notice alleged that the '703 patent was invalid or that Lupin's proposed generic product would not infringe the '703 patent.

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[48] FDA Final Approval Letter Concerning Lupin's ANDA No. 090051, dated April 10, 2015 ("This is in reference to your abbreviated new drug application (ANDA) received on October 16, 2007, and submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Memantine Hydrochloride Tablets USP, 5 mg and 10 mg.") attached as Exhibit 9 to the Litvin Declaration.

[49] Complaint, *Forest Laboratories, Inc., et al. v. Cobalt Laboratories Inc., et al.*, 08-cv-00021 (D. De) (ECF No. 1, filed Jan. 10, 2008) (hereinafter "'021 Complaint"), attached to as Exhibit 10 to the Litvin Declaration, at ¶ 38 (alleging that Lupin's ANDA contained a Paragraph IV certification).

[50] *Id*. at ¶ 38.

[51] FDA Final Approval Letter Concerning Lupin's ANDA No. 090051, dated April 10, 2015 ("Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '703 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Memantine Hydrochloride Tablets USP, 5 mg and 10 mg, under this ANDA.").

49. On January 10, 2008, Forest and Merz filed a Hatch-Waxman lawsuit in the United States District Court for the District of Delaware against Lupin (as well as co-defendants Orchid, Teva, and others) alleging infringement of the '703 patent. This became Case No. 08-cv-00021 (D. Del.).[52]

Response: Not disputed.

50. On June 2, 2008, case No. 08-cv-00052 (D. Del.), which was brought against other generic ANDA filers, including Dr. Reddy's, Amneal, Mylan, and Sun,[53] was consolidated into the suit against Lupin, case No. 08-cv-00021 (D. Del.), with the '021 case becoming the lead case.[54]

Response: Not disputed.

51. In December 2009, Forest and Merz settled with Lupin.[55]

Response: Not disputed.

52. In connection with this settlement, Lupin agreed, among other things, to discontinue its efforts to challenge the '703 patent.[56]

Response: Disputed as incomplete and misleading. The settlement between Forest and Lupin provided

See Lupin Settlement Agreement, at § 6, Litvin Ex. 11. The parties also agreed

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[52] *See* '021 Complaint.

[53] *See* '052 Complaint.

[54] Order of Consolidation, *Forest Laboratories, Inc., et al. v. Cobalt Laboratories Inc., et al.*, 08-cv-00021 (D. De) (ECF No. 76, filed June 2, 2008).

[55] *See* Settlement Agreement with Lupin, dated Dec. 11, 2009, FRX-AT-00000340 - FRX-AT-00000379, attached as Exhibit 11 to the Litvin Declaration (hereinafter "Lupin Settlement").

[56] *Id*. at 2-3 (FRX-AT-00000341 – FRX-AT-00000342)

See id., Exhibit B (License Agreement), at §§ 1.12, 2.1, 3.2.

53. Also in connection with this settlement, Lupin agreed to not launch its generic product until the exact same day, on January 11, 2015, that the other 6 of the 7 Generic Companies agreed to launch.[57]

Response: Forest disputes that its settlement with Lupin was an "agree[ment] to not launch" Lupin's proposed generic product. Consistent with the U.S. patent laws and the Hatch-Waxman Act, Forest sued Lupin under 35 U.S.C. § 271(e) alleging infringement of the presumptively valid '703 patent. Pursuant to the parties' settlement of that litigation, Forest granted Lupin a

[57] *Id*., at Ex. B (License Agreement) (FRX-AT -00000360, FRX-AT-00000361- FRX-AT-00000362, FRX-AT-00000364 - FRX-AT-00000365) ("1.12 'Launch Date' shall mean the later of: (a) 3 calendar months prior to the expiration of the '703 Patent, including any extensions and/or pediatric exclusivity, whether granted before, on or after the Execution Date; or (b) the date that Lupin obtains final approval from the FDA of the Lupin ANDA, unless accelerated as described in Sections 4.4 and 4.5 herein. . . .

license to the '703 patent, enabling Lupin to begin selling its product

. See Lupin Settlement Agreement, at § 2, Litvin Ex. 11; Id., Exhibit B (License Agreement), at §§ 1.12, 2.1, 3.2.

54. This agreement, along with the agreements of the other 6 of the 7 Generic Companies, contained a provision that extended the agreed-upon generic launch date from January 11, 2015 to July 11, 2015 in the event that, subsequent to the consummation of the execution of these agreements, Forest was granted an additional six-month pediatric exclusivity period for Namenda.[58]

Response: Not disputed.

55. Lupin, along with the other 6 of the 7 Generic Companies, maintained its Paragraph IV certification to the '703 Patent.[59]

Response: Forest does not dispute Plaintiffs' quotation of the FDA approval letter for Lupin's ANDA No. 090051 (in footnote 59), but clarifies that Lupin's ANDA did not contain a Paragraph IV certification after the '703 patent expired. See 21 U.S.C. § 355a(c)(1)(B)(i)(I); see also Mylan Labs., 389 F.3d at 1278 ("when [NDA holder]'s patent expired [generic company]'s paragraph IV certification would no longer be accurate and [generic company] would be required to amend it, or . . . FDA can treat that certification as automatically amended to contain a paragraph II certification[.]").

56. The FDA granted final approval of Lupin's ANDA on April 10, 2015.[60]

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[58] *Id*.

[59] FDA Final Approval Letter Concerning Lupin's ANDA No. 090051, dated April 10, 2015 ("Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '703 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Memantine Hydrochloride Tablets USP, 5 mg and 10 mg, under this ANDA.")

[60] *Id*. ("the ANDA is approved, effective on the date of this letter").

Response: Forest does not dispute that the FDA sent Lupin a letter on April 10, 2015 stating that "the [Lupin] ANDA is approved" but disputes that the approval is properly considered "final," as explained in Forest's Brief, in Section III(C)(3).

57. The FDA never rescinded Lupin's final approval.[61]

Response: Disputed. The current version of the FDA's electronic Orange Book is not evidence that the FDA never rescinded or otherwise adjusted the approval it granted Lupin on April 10, 2015. Forest further disputes that the approval of Lupin's ANDA granted on April 10, 2015 is properly considered "final," as explained in Forest's Brief, in Section III(C)(3).

58. By July 13, 2015, Lupin began commercially marketing immediate release Namenda tablets in the U.S.[62]

Response: Disputed. Plaintiffs have not proven that the cited website confirms the date as of which Lupin began selling its generic version of Namenda or that the website itself is admissible evidence and therefore appropriate for consideration under FRCP 56(c)(2) ("A party may object that the material cited to support or dispute a fact cannot be presented in a form that would be admissible in evidence.").

D. Mylan

59. Mylan submitted its ANDA in October, 2007.[63]

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[61] Current FDA Electronic Orange Book, Product Details for Lupin's ANDA No. 090051 (providing that the FDA approved Lupin's ANDA on April 10, 2015) (available at http://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=090051#).

[62] FDA National Drug Code Directory, available at http://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm, identifies July 13, 2015 as the "Start Marketing Date" for Lupin's ANDA No. 090051.

[63]

Response: Not disputed.

60. Mylan filed a Paragraph IV certification with its ANDA.[64]

Response: Not disputed.

61. Mylan sent its Paragraph IV notice to Forest and Merz on December 18, 2007.[65]

Response: Not disputed.

62. This Paragraph IV certification provided that the '703 patent was invalid and/or not infringed by Mylan's products.[66]

Response: Disputed that Mylan's Paragraph IV notice "provided" for invalidity or non-infringement of the '703 patent. Rather, Mylan's Paragraph IV notice alleged that the '703 patent was invalid or that Mylan's proposed generic product would not infringe the '703 patent.

63. On January 25, 2008, Forest and Merz filed a Hatch-Waxman lawsuit in the United States District Court for the District of Delaware against Mylan (as well as co-defendants Interpharm (now Amneal), Dr. Reddy's, and Sun) alleging infringement of the '703 patent.[67] This became Case No. 08-cv-00052 (D. Del.).[68]

Response: Not disputed.

64. On June 2, 2008, the lawsuit against Mylan was consolidated into case No. 08-cv-00021 (a similar Hatch –Waxman lawsuit against Lupin, Orchid, Teva, and others), with the '021 case becoming the lead case.[69]

Response: Not disputed.

65. In July 2010, Forest and Merz settled with Mylan.[70]

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64 '052 Complaint, at ¶ 60 (alleging that Mylan's ANDA contained a Paragraph IV certification).

65 *Id*.

66 *Id*.

67 *Id*. at ¶¶ 51-58.

68 *Id*. at ¶¶ 59-64.

69 Order of Consolidation, *Forest Laboratories, Inc., et al. v. Cobalt Laboratories Inc., et al.*, 08-cv-00021 (D. Del.) (ECF No. 76, filed June 2, 2008).

Response: Not disputed.

66. In connection with this settlement, Mylan agreed, among other things, to discontinue its efforts to challenge the '703 patent.[71]

Response: Disputed as incomplete and misleading. The settlement between Forest and Mylan provided

. See Mylan Settlement Agreement, at § 6, Litvin Ex. 13. The parties also agreed

. See id., Exhibit B (License Agreement), at §§ 1.13, 2.1, 3.2.

67. Also in connection with this settlement, Mylan agreed to not launch its generic product until the exact same day, on January 11, 2015, that the other 6 of the 7 Generic Companies agreed to launch.[72]

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[70] *See* Settlement Agreement with Mylan, dated July 21, 2010, FRX-AT-00000428 - FRX-AT-00000463, (hereinafter "Mylan Settlement") attached as Exhibit 13 to the Litvin Declaration.

[71] Mylan Settlement, at 2-3 (FRX-AT-0000429)

[72] *Id*. at Ex. B (License Agreement) (FRX-AT-00000447, FRX-AT -00000448 - FRX-AT-00000449) ("1.13 'Launch Date' shall mean the later of: (a) three (3) calendar months prior to the expiration of the '703 Patent, including any extensions and/or pediatric exclusivity, whether granted before, on or after the Execution Date; or (b) the date that Mylan obtains final approval from the FDA of the Mylan ANDA, unless accelerated as described herein. . . .

Response: Forest disputes that its settlement with Mylan was an "agree[ment] to not launch" Mylan's proposed generic product. Consistent with the U.S. patent laws and the Hatch-Waxman Act, Forest sued Mylan under 35 U.S.C. § 271(e) alleging infringement of the presumptively valid '703 patent. Pursuant to the parties' settlement of that litigation, Forest granted Mylan a license to the '703 patent, enabling Mylan to begin selling its product

. See Mylan Settlement Agreement, at § 2, Litvin Ex. 13; Id., Exhibit B (License Agreement), at §§ 1.13, 2.1, 3.2.

68. This agreement, along with the agreements of the other 6 of the 7 Generic Companies, contained a provision that extended the agreed-upon generic launch date from January 11, 2015 to July 11, 2015 in the event that, subsequent to the consummation of the execution of these agreements, Forest was granted an additional six-month pediatric exclusivity period for Namenda.[73]

Response: Not disputed.

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[73] *Id.*

69. Mylan, along with the other 6 of the 7 Generic Companies, maintained its Paragraph IV certification to the '703 Patent.[74]

Response: Forest does not dispute Plaintiffs' quotation of the FDA approval letter for Mylan's ANDA No. 079225 (in footnote 74), but clarifies that Mylan's ANDA did not contain a Paragraph IV certification after the '703 patent expired. See 21 U.S.C. § 355a(c)(1)(B)(i)(I); see also Mylan Labs., 389 F.3d at 1278 ("when [NDA holder]'s patent expired [generic company]'s paragraph IV certification would no longer be accurate and [generic company] would be required to amend it, or . . . FDA can treat that certification as automatically amended to contain a paragraph II certification[.]").

70. The FDA granted final approval of Mylan's ANDA on January 30, 2015.[75]

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[74] '052 Complaint, at ¶ 60 (alleging that Mylan's ANDA contained a PIV certification "that the claims of the '703 patent are invalid, unenforceable and/or not infringed by the commercial manufacture, use or sale of the Mylan Generic Products."); *See also* Mylan Settlement, at 2-3 (FRX-AT-0000429)

Ex. A (Proposed Stipulation and Order) (FRX-AT-00000441)

[75] Current FDA Electronic Orange Book, Product Details for Mylan's ANDA No. 079225 (providing that the FDA approved Mylan's ANDA on Jan. 30, 2015) (available at http://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=079225#).

Response: Forest does not dispute that the FDA sent Mylan a letter on January 30, 2015 stating that "the [Mylan] ANDA is approved" but disputes that the approval is properly considered "final," as explained in Forest's Brief, in Section III(C)(3).

71. The FDA never rescinded Mylan's final approval.[76]

Response: Disputed. The current version of the FDA's electronic Orange Book is not evidence that the FDA never rescinded or otherwise adjusted the approval it granted Mylan on January 30, 2015. Forest further disputes that the approval of Mylan's ANDA granted on January 30, 2015 is properly considered "final," as explained in Forest's Brief, in Section III(C)(3).

72. By July 11, 2015, Mylan began commercially marketing immediate release Namenda tablets in the U.S.[77]

Response: Disputed. Plaintiffs have not proven that the cited website confirms the date as of which Mylan began selling its generic version of Namenda or that the website itself is admissible evidence and therefore appropriate for consideration under FRCP 56(c)(2) ("A party may object that the material cited to support or dispute a fact cannot be presented in a form that would be admissible in evidence.").

E. Orchid

73. Orchid submitted its ANDA on October 16, 2007.[78]

Response: Not disputed.

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[76] *Id.*

[77] FDA National Drug Code Directory, available at http://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm, identifies July 11, 2015 as the "Start Marketing Date" for Mylan's ANDA No. 079225.

[78] FDA Final Approval Letter Concerning Orchid's ANDA No. 090044, dated March 12, 2012 ("This is in reference to your abbreviated new drug application (ANDA) dated October 16, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Memantine Hydrochloride Tablets, 5 mg and 10 mg.") attached as Exhibit 14 to the Litvin Declaration.

74. Orchid filed a Paragraph IV certification with its ANDA.[79]

Response: Not disputed.

75. Orchid sent its Paragraph IV notice to Forest and Merz on December 11, 2007.[80]

Response: Not disputed.

76. This Paragraph IV certification provided that the '703 patent was invalid and/or not infringed by Orchid's products.[81]

Response: Disputed that Orchid's Paragraph IV notice "provided" for invalidity or non-infringement of the '703 patent. Rather, Orchid's Paragraph IV notice alleged that the '703 patent was invalid or that Orchid's proposed generic product would not infringe the '703 patent.

77. On January 10, 2008, Forest and Merz filed a Hatch-Waxman lawsuit in the United States District Court for the District of Delaware against Orchid and (as well as co-defendants Lupin, Teva, and others) alleging infringement of the '703 patent. This became Case No. 08-cv-00021 (D. Del.).[82]

Response: Not disputed, but Forest clarifies that the litigation against Orchid was transferred to the United States District Court for the District of New Jersey, i.e., Forest Labs., Inc., et al. v. Orgenus Pharma Inc., et al., 09-cv-5105 (D.N.J.).

78. In June 2008, case No. 08-cv-00052 (D. Del.), which was brought against other generic ANDA filers, including Dr. Reddy's, Amneal, Mylan and Sun,[83] was

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[79] '021 Complaint, at ¶ 46 (alleging that Orchid's ANDA contained a Paragraph IV certification).

[80] *Id*.

[81] FDA Final Approval Letter Concerning Orchid's ANDA No. 90044, dated March 12, 2012, p. 2 ("Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '703 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Memantine Hydrochloride Tablets, 5 mg and 10 mg, under this ANDA.").

[82] *See* '021 Complaint.

[83] '052 Complaint, at 1.

consolidated into the suit against Orchid, case No. 08-cv-00021 (D. Del.), with the '021 case becoming the lead case.[84]

Response: Not disputed, but Forest clarifies that the litigation against Orchid was transferred to the United States District Court for the District of New Jersey, i.e., Forest Labs., Inc., et al. v. Orgenus Pharma Inc., et al., 09-cv-5105 (D.N.J.).

79. In April 2010, Forest and Merz settled with Orchid.[85]

Response: Not disputed.

80. In connection with this settlement, Orchid agreed, among other things, to discontinue its efforts to challenge the '703 patent.[86]

Response: Disputed as incomplete and misleading. The settlement between Forest and Orchid provided

See Orchid Settlement Agreement, at § 6, Litvin Ex. 15. The parties also agreed

See id., Exhibit B (License Agreement), at §§ 1.14, 2.1, 3.2.

81. Also in connection with this settlement, Orchid agreed to not launch its generic product until the exact same day, on January 11, 2015, that the other 6 of the 7 Generic Companies agreed to launch.[87]

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[84] Order of Consolidation, *Forest Laboratories, Inc., et al. v. Cobalt Laboratories Inc., et al.*, 08-cv-00021 (D. Del.) (ECF No. 76, filed June 2, 2008).

[85] Settlement Agreement with Orchid, dated March 23, 2010, FRX-AT-00000380 - FRX-AT-00000416, (hereinafter "Orchid Settlement") attached as Exhibit 15 to the Litvin Declaration.

[86] *Id*. at 2-3 (FRX-AT-00000381 - FRX-AT-00000382)

Response: Forest disputes that its settlement with Orchid was an "agree[ment] to not launch" Orchid's proposed generic product. Consistent with the U.S. patent laws and the Hatch-Waxman Act, Forest sued Orchid under 35 U.S.C. § 271(e) alleging infringement of the presumptively valid '703 patent. Pursuant to the parties' settlement of that litigation, Forest granted Orchid a license to the '703 patent, enabling Orchid to begin selling its product

See Orchid Settlement Agreement, at § 2, Litvin Ex. 15; Id., Exhibit B (License Agreement), at §§ 1.14, 2.1, 3.2.

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[87] *Id.* at Ex. B (License Agreement) (FRX-AT-00000398, FRX-AT-00000400) ("1.14 'Launch Date' shall mean the later of: (a) 3 calendar months prior to the expiration of the '703 Patent, including any extensions and/or pediatric exclusivity, whether granted before, on or after the Execution Date; or (b) the date that Orchid obtains final approval from the FDA of the Orchid ANDA, unless accelerated as described herein. . . .

82. This agreement, along with the agreements of the other 6 of the 7 Generic Companies, contained a provision that extended the agreed-upon generic launch date from January 11, 2015 to July 11, 2015 in the event that, subsequent to the consummation of the execution of these agreements, Forest was granted an additional six-month pediatric exclusivity period for Namenda.[88]

Response: Not disputed.

83. Orchid, along with the other 6 of the 7 Generic Companies, maintained its Paragraph IV certification to the '703 Patent.[89]

Response: Forest does not dispute Plaintiffs' quotation of the FDA approval letter for Orchid's ANDA No. 90044 (in footnote 89), but clarifies that Orchid's ANDA did not contain a Paragraph IV certification after the '703 patent expired. See 21 U.S.C. § 355a(c)(1)(B)(i)(I); see also Mylan Labs., 389 F.3d at 1278 ("when [NDA holder]'s patent expired [generic company]'s paragraph IV certification would no longer be accurate and [generic company] would be required to amend it, or . . . FDA can treat that certification as automatically amended to contain a paragraph II certification[.]").

84. The FDA granted final approval of Orchid's ANDA on March 12, 2012.[90]

Response: Forest does not dispute that the FDA sent Orchid a letter on March 12, 2012 stating that "the [Orchid] ANDA is approved" but disputes that the approval is properly considered "final," as explained in Forest's Brief, in Section III(C)(3).

85. The FDA never rescinded Orchid's final approval.[91]

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[88] Id.

[89] FDA Final Approval Letter Concerning Orchid's ANDA No. 90044, dated March 12, 2012 ("Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '703 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Memantine Hydrochloride Tablets, 5 mg and 10 mg, under this ANDA.").

[90] FDA Final Approval Letter Concerning Orchid's ANDA No. 90044, dated March 12, 2012 ("the ANDA is approved, effective on the date of this letter").

Response: Disputed. The current version of the FDA's electronic Orange Book is not evidence that the FDA never rescinded or otherwise adjusted the approval it granted Orchid on March 12, 2012. Forest further disputes that the approval of Orchid's ANDA granted on March 12, 2012 is properly considered "final," as explained in Forest's Brief, in Section III(C)(3).

F. Sun

86. By no later than December 20, 2007, Sun submitted its ANDA.[92]

Response: Not disputed.

87. Sun filed a Paragraph IV certification with its ANDA.[93]

Response: Not disputed.

88. Sun sent its Paragraph IV notice to Forest and Merz on December 20, 2007.[94]

Response: Not disputed.

89. This Paragraph IV certification provided that the '703 patent was invalid and/or not infringed by Sun's products.[95]

Response: Disputed that Sun's Paragraph IV notice "provided" for invalidity or non-infringement of the '703 patent. Rather, Sun's Paragraph IV notice alleged that the '703 patent was invalid or that Sun's proposed generic product would not infringe the '703 patent.

90. On January 25, 2008, Forest and Merz filed a Hatch-Waxman lawsuit in the United States District Court for the District of Delaware against Sun (as well as

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[91] Current FDA Electronic Orange Book, Product Details for Orchid's ANDA No. 90044 (providing that FDA approved Orchid's ANDA No. 90044 on March 12, 2012) (available at http://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=090044#).

[92] '052 Complaint, at ¶ 74 (Sun sent its PIV notice associated with its ANDA on or before Dec. 20, 2007).

[93] *Id*. (alleging Sun's ANDA contained a Paragraph IV certification).

[94] *Id*.

[95] *Id*.

co-defendants Interpharm (now Amneal), and Dr. Reddy's) alleging infringement of the '703 patent.[96] This became Case No. 08-cv-00052 (D. Del.).[97]

Response: Not disputed.

91. On June 2, 2008, the lawsuit against Mylan was consolidated into case No. 08-cv-00021 (a similar Hatch –Waxman lawsuit against Lupin, Orchid, Teva, and others), with the '021 case becoming the lead case.[98]

Response: Not disputed.

92. In October 2009, Forest and Merz settled with Sun.[99]

Response: Not disputed.

93. In connection with this settlement, Sun agreed, among other things, to discontinue its efforts to challenge the '703 patent.[100]

Response: Disputed as incomplete and misleading. The settlement between Forest and Sun provided

See Sun Settlement Agreement, at § 5, Litvin Ex. 16.

See id., Exhibit B (License Agreement), at §§ 1.12, 2.1, 3.2.

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96 *Id*. at ¶ 51-58.

97 *Id*.

98 Order of Consolidation, *Forest Laboratories, Inc., et al. v. Cobalt Laboratories Inc., et al.*, 08-cv-00021 (D. Del.) (ECF No. 76, filed June 2, 2008).

99 *See* Settlement Agreement with Sun, dated Oct. 9, 2009, FRX-AT-00000112 - FRX-AT-00000147, (hereinafter "Sun Settlement") attached as Exhibit 16 to the Litvin Declaration.

100 Sun Settlement , at 3 (FRX-AT-000000114)

94. Also in connection with this settlement, Sun agreed to not launch its generic product until the exact same day, on January 11, 2015, that the other 6 of the 7 Generic Companies agreed to launch.[101]

Response: Forest disputes that its settlement with Sun was an "agree[ment] to not launch" Sun's proposed generic product. Consistent with the U.S. patent laws and the Hatch-Waxman Act, Forest sued Sun under 35 U.S.C. § 271(e) alleging infringement of the presumptively valid '703 patent. Pursuant to the parties' settlement of that litigation, Forest granted Sun a license to the '703 patent, enabling Sun to begin selling its product

[101] *Id*. at Ex. B (License Agreement) (FRX-AT-00000130, FRX-AT-00000132, FRX-AT-00000134) ("1.12 'Launch Date' shall mean the later of: (a) 3 calendar months prior to the expiration of the '703 Patent, including any extensions and/or pediatric exclusivity, whether granted before, on or after the Execution Date; or (b) the date that Sun obtains final approval from the FDA of the Sun ANDA, unless accelerated as described herein. . . .

. See Sun Settlement Agreement, at § 2, Litvin Ex. 16; Id., Exhibit B (License Agreement), at §§ 1.12, 2.1, 3.2.

95. This agreement, along with the agreements of the other 6 of the 7 Generic Companies, contained a provision that extended the agreed-upon generic launch date from January 11, 2015 to July 11, 2015 in the event that, subsequent to the consummation of the execution of these agreements, Forest was granted an additional six-month pediatric exclusivity period for Namenda.[102]

Response: Not disputed.

96. Sun, along with the other 6 of the 7 Generic Companies, maintained its Paragraph IV certification to the '703 Patent.[103]

Response: Forest does not dispute Plaintiffs' quotation of the FDA approval letter for Sun's ANDA No. 090058 (in footnote 103), but clarifies that Sun's ANDA did not contain a Paragraph IV certification after the '703 patent expired. See 21 U.S.C. § 355a(c)(1)(B)(i)(I); see also Mylan Labs., 389 F.3d at 1278 ("when [NDA holder]'s patent expired [generic company]'s paragraph IV certification would no longer be accurate and [generic company] would be required

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[102] *Id*.

[103] '052 Complaint, at ¶ 74 (alleging Sun's ANDA contained a Paragraph IV certification). *See also* Sun Settlement, at 3 (FRX-AT-000000114)

Ex. A (Proposed Stipulation and Order) (FRX-AT-00000125)

to amend it, or . . . FDA can treat that certification as automatically amended to contain a paragraph II certification[.]").

97. The FDA granted final approval of Sun's ANDA on May 5, 2010.[104]

Response: Forest does not dispute that the FDA sent Sun a letter on May 5, 2010 stating that "the [Sun] ANDA is approved" but disputes that the approval is properly considered "final," as explained in Forest's Brief, in Section III(C)(3).

98. The FDA never rescinded Sun's final approval.[105]

Response: Disputed. The current version of the FDA's electronic Orange Book is not evidence that the FDA never rescinded or otherwise adjusted the approval it granted Sun on May 5, 2010. Forest further disputes that the approval of Sun's ANDA granted on May 5, 2010 is properly considered "final," as explained in Forest's Brief, in Section III(C)(3).

99. By July 11, 2015, Sun began commercially marketing immediate release Namenda tablets in the U.S.[106]

Response: Disputed. Plaintiffs have not proven that the cited website confirms the date as of which Sun began selling its generic version of Namenda or that the website itself is admissible evidence and therefore appropriate for consideration under FRCP 56(c)(2) ("A party may object that the material cited to support or dispute a fact cannot be presented in a form that would be admissible in evidence.").

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[104] Current FDA Electronic Orange Book, Product Details for Sun's ANDA No. 090058 (providing that FDA approved Sun's ANDA No. 090058 on May 5, 2010) (available at http://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=090058#).

[105] *Id*.

[106] FDA National Drug Code Directory, available at http://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm, identifies July 11, 2015 as the "Start Marketing Date" for Sun's ANDA No. 090058.

G. Teva

100. By no later than November 30, 2007, Teva submitted its ANDA.[107]

Response: Not disputed.

101. Teva filed a Paragraph IV certification with its ANDA.[108]

Response: Not disputed.

102. Teva sent its Paragraph IV notice to Forest and Merz on November 30, 2007.[109]

Response: Not disputed.

103. This Paragraph IV certification provided that the '703 patent was invalid and/or not infringed by Teva's products.[110]

Response: Disputed that Teva's Paragraph IV notice "provided" for invalidity or non-infringement of the '703 patent. Rather, Teva's Paragraph IV notice alleged that the '703 patent was invalid or that Teva's proposed generic product would not infringe the '703 patent.

104. On January 10, 2008, Forest and Merz filed a Hatch-Waxman lawsuit in the United States District Court for the District of Delaware against Teva (as well as co-defendants Lupin, Orchid, and others) alleging infringement of the '703 patent. This became Case No. 08-cv-00021 (D. Del.).[111]

Response: Not disputed.

105. In June 2008, case No. 08-cv-00052 (D. Del.), which was brought against other generic ANDA filers, including Dr. Reddy's, Amneal, Mylan, and Sun,[112] was

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[107] '021 Complaint, at ¶ 54 (Teva sent the PIV notice associated with its ANDA on or before November 30, 2007).

[108] '021 Complaint, at ¶ 54 (alleging that Teva's ANDA contained a Paragraph IV certification).

[109] *Id.*

[110] *Id.*

[111] *See* '021 Complaint.

[112] '052 Complaint, at 1.

consolidated into the suit against Teva, case No. 08-cv-00021 (D. Del.), with the '021 case becoming the lead case.[113]

Response: Not disputed.

106. In November 2009, Forest and Merz settled with Teva.[114]

Response: Not disputed.

107. In connection with this settlement, Teva agreed, among other things, to discontinue its efforts to challenge the '703 patent.[115]

Response: Disputed as incomplete and misleading. The settlement between Forest and Teva provided

See Teva Settlement Agreement, at § 5, Litvin Ex. 17. The parties also agreed

. See id., Exhibit B (License Agreement), at §§ 1.14, 2.1, 3.2.

108. Also in connection with this settlement, Teva agreed to not launch its generic product until the exact same day, on January 11, 2015, that the other 6 of the 7 Generic Companies agreed to launch.[116]

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[113] Order of Consolidation, *Forest Laboratories, Inc., et al. v. Cobalt Laboratories Inc., et al.*, 08-cv-00021 (D. Del.) (ECF No. 76, filed June 2, 2008).

[114] Settlement Agreement with Teva, dated Nov. 3, 2009, FRX-AT-00000184 - FRX-AT-00000217, (hereinafter "Teva Settlement") attached as Exhibit 17 to the Litvin Declaration.

[115] *Id*. at 2 (FRX-AT-00000185)

[116] Teva Settlement, at Ex. B (License Agreement) (FRX-AT -00000202, FRX-AT -00000208) (1.14 "'Launch Date' shall mean three (3) calendar months prior to the later of (a) expiration of the '703 Patent, including any extensions thereof; and (b) any pediatric exclusivity period attached to the '703 Patent, whether such extension or pediatric exclusivity was granted before, on, or after the Execution Date, unless accelerated as described herein in Sections 4.3-

Response: Forest disputes that its settlement with Teva was an "agree[ment] to not launch" Teva's proposed generic product. Consistent with the U.S. patent laws and the Hatch-Waxman Act, Forest sued Teva under 35 U.S.C. § 271(e) alleging infringement of the presumptively valid '703 patent. Pursuant to the parties' settlement of that litigation, Forest granted Teva a license to the '703 patent, enabling Teva to begin selling its product

. See Teva Settlement Agreement, at § 2, Litvin Ex. 17; Id., Exhibit B (License Agreement), at §§ 1.14, 2.1, 3.2.

109. This agreement, along with the agreements of the other 6 of the 7 Generic Companies, contained a provision that extended the agreed-upon generic launch date from January 11, 2015 to July 11, 2015 in the event that, subsequent to the consummation of the execution of these agreements, Forest was granted an additional six-month pediatric exclusivity period for Namenda.[117]

Response: Not disputed.

4.6. . . .

[117] *Id.*

110. Teva, along with the other 6 of the 7 Generic Companies, maintained its Paragraph IV certification to the '703 Patent despite settling its patent lawsuit with Forest.[118]

Response: Forest does not dispute Plaintiffs' quotation of the FDA approval letter for Teva's ANDA No. 090052 (in footnote 119), but clarifies that Teva's ANDA did not contain a Paragraph IV certification after the '703 patent expired. See 21 U.S.C. § 355a(c)(1)(B)(i)(I); see also Mylan Labs., 389 F.3d at 1278 ("when [NDA holder]'s patent expired [generic company]'s paragraph IV certification would no longer be accurate and [generic company] would be required to amend it, or . . . FDA can treat that certification as automatically amended to contain a paragraph II certification[.]").

111. The FDA granted final approval of Teva's ANDA on October 25, 2011.[119]

Response: Forest does not dispute that the FDA sent Teva a letter on October 25, 2011 stating that "the [Teva] ANDA is approved" but disputes that the approval is properly considered "final," as explained in Forest's Brief, in Section III(C)(3).

112. The FDA never rescinded Teva's final approval.[120]

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[118] '021 Complaint, at ¶ 54 (alleging that Teva's ANDA contained a Paragraph IV certification). *See also* Teva Settlement, at 2 (FRX-AT-00000185)

, Ex. A (Proposed Stipulation and Order), at 3-4 (FRX-AT-00000198 – FRX-AT-00000199)

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[119] Current FDA Electronic Orange Book, Product Details for Teva's ANDA No. 090052 (providing that the FDA approved Teva's ANDA No. 090052 on Oct. 25, 2011) (available at http://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=090052#).

[120] *Id.*

Response: Disputed. The current version of the FDA's electronic Orange Book is not evidence that the FDA never rescinded or otherwise adjusted the approval it granted Teva on October 25, 2011. Forest further disputes that the approval of Teva's ANDA granted on October 25, 2011 is properly considered "final," as explained in Forest's Brief, in Section III(C)(3).

FOREST'S COUNTER-STATEMENT OF UNDISPUTED FACTS IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT ON COUNT THREE

I. Pediatric Exclusivity for Namenda®

113. On January 25, 2012, the FDA requested that Forest conduct studies evaluating the use of memantine hydrochloride – the active pharmaceutical ingredient in Namenda® - in pediatric patients suffering from autism. *See* Letter from Robert Temple (FDA) to Kathleen Waldron (Forest Labs., Inc., Associate Director) (Jan. 25, 2012), Adam Ex. 3.

114. Forest conducted studies evaluating the use of memantine hydrochloride on pediatric patients suffering from autism. Forest spent approximately $70 million on these pediatric studies. See Saunders Dep. 318:13-17, Adam Ex. 4, FRX-AT-01730585; Taglietti Declaration, Adam Ex. 5, FRX-AT-01764620.

115. The FDA determined that Forest's pediatric memantine hydrochloride studies sufficiently met the requirements of the pediatric exclusivity statute and, in turn, awarded Forest pediatric exclusivity. See FDA, Pediatric Exclusivity Granted, available at: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm050005.htm (February 2017), at line 127, Adam Ex. 6.

116. On June 16, 2014, the FDA awarded Forest pediatric exclusivity for Namenda®. See id., at line 127, Adam Ex. 6. The FDA then updated the Orange Book to reflect this additional exclusivity. FDA, Approved Drug Products with Therapeutic Equivalence Evaluations, at 132-133 (35th ed. 2015), Adam Ex. 25.

II. Namenda® Patent Litigation: Settlements, District Court Orders, and FDA Approval

117. On January 10, 2008, Forest filed a patent infringement lawsuit for infringement of the '703 patent against Cobalt Laboratories Inc. ("Cobalt"), Lupin, Orchid, Teva, Upsher-Smith Laboratories, Inc. ("Upsher Smith"), and Wockhardt USA Inc. and Wockhardt Ltd. (collectively, "Wockhardt") after those generic companies submitted ANDAs for proposed generic versions of Namenda® that contained Paragraph IV certifications against Forest's '703 patent. See Forest Labs., Inc. et al. v. Cobalt Labs. Inc., et al., 08-cv-021, D.I. 1, Complaint (D. Del.).

118. On January 25, 2008, Forest filed a patent infringement lawsuit for infringement of the '703 patent against, inter alia, Dr. Reddy's, Amneal, Mylan, Sun (together with the generic defendants in the 08-00021 case, the "Generics") after those generic companies submitted ANDAs for proposed generic versions of Namenda® that contained Paragraph IV certifications against Forest's '703 patent. See Forest Labs., Inc., et al., v. Dr. Reddy's Labs., Inc., et al., 08-cv-052, D.I. 1, Complaint (D. Del.). The two cases were eventually consolidated. See id, D.I. 91, Order of Consolidation.

119. By submitting Paragraph IV certifications, the Generics requested FDA approval to market their generic product prior to the expiry of the '703 patent on April 11, 2015. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

120. In the patent litigation underlying this case, Magistrate Judge Leonard Stark issued a Report and Recommendation (the "R&R") concerning claim construction. See Forest Labs., Inc. v. Cobalt Labs Inc., 08-cv-021, D.I. 373, 2009 U.S. Dist. LEXIS 56368 (D. Del. July 2, 2009). In the R&R, Magistrate Judge Stark adopted Forest's position – or language that was the equivalent of Forest's position – for nine of thirteen disputed terms. See id. Judge Sleet then

issued a memorandum and order, which agreed almost entirely with the R&R. See Forest Labs. Inc. v. Cobalt Labs Inc., No. 08-cv-00021-GMS-LPS, D.I. 426, 2009 U.S. Dist. LEXIS 86772 (D. Del. Sept. 21, 2009).

A. Amneal

121. Forest's settlement with Amneal allows Amneal to launch a generic memantine hydrochloride product the later of

Amneal Settlement Agreement, Exhibit B (License Agreement), at § 1.14, 2.1, 3.2, Litvin Ex. 3.

122. Amneal was eligible to begin marketing (per the settlement agreement, without accounting for any required FDA approval) a generic memantine hydrochloride product by July 11, 2015 *Id.*; PSOF30. This was three-months prior to October 11, 2015, the date on which pediatric exclusivity for the '703 patent would have expired. *See Forest Labs., Inc. v. Cobalt Labs., Inc.*, 08-cv-021, D.I. 418 (D. Del.) (the "Amneal Order"), at 3-4, Adam Ex. 7.

123. After the execution of a settlement between Forest and Amneal, the district court entered a Stipulation and Order, which "finally resolve[d]" the litigation. *See* Amneal Order, at 4, Adam Ex. 7.

124. The Amneal Order is a final, un-appealable judgment, in which Amneal stipulated that its Paragraph IV ANDA filing constituted an act of infringement and it had not "rebutted the statutory presumption that the '703 patent is valid and enforceable." Amneal Order, at 2, Adam Ex. 7.

125. The Amneal Order further includes a permanent injunction, which reads:

> Amneal, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them . . . are hereby enjoined from manufacturing, using, offering to sell or

> selling within the United States, or importing into the United States, the generic tablet products . . . that are the subject of ANDA No. 90-041 during the life of the '703 patent, including any extensions and pediatric exclusivities, absent a license agreement or other authorization by Plaintiffs[.]

Amneal Order, at 3-4, Adam Ex. 7.

B. Cobalt

126. Forest's settlement with Cobalt allows Cobalt to launch a generic memantine hydrochloride product the later of

Cobalt Settlement Agreement, Exhibit B (License Agreement), at § 1.15, 2.1, 3.2, Adam Ex. 8.

127. Cobalt was eligible to begin marketing (per the settlement agreement, without accounting for any required FDA approval) a generic memantine hydrochloride product by July 11, 2015. *Id.* This was three-months prior to October 11, 2015, the date on which pediatric exclusivity for the '703 patent would have expired. *See Forest Labs., Inc. v. Cobalt Labs., Inc.*, 08-cv-021, D.I. 439 (D. Del.) (the "Cobalt Order"), at 3-4, Adam Ex. 9.

128. After the execution of a settlement between Forest and Cobalt, the district court entered a Stipulation and Order, which "finally resolve[d]" the litigation. *See* Cobalt Order, at 4, Adam Ex. 9.

129. The Cobalt Order is a final, un-appealable judgment, in which Cobalt stipulated that its Paragraph IV ANDA filing constituted an act of infringement and it had not "rebutted the statutory presumption that the '703 patent is valid and enforceable." Cobalt Order, at 2, Adam Ex. 9.

130. The Cobalt Order further includes a permanent injunction, which reads:

> Cobalt, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them . . . are

> hereby enjoined from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, the generic tablet products . . . that are the subject of ANDA No. 90-042 during the life of the '703 patent, including any extensions and pediatric exclusivities, absent a license agreement or other authorization by Plaintiffs[.]

Cobalt Order, at 3-4, Adam Ex. 9.

C. Dr. Reddy's

131. Forest's settlement with Dr. Reddy's allows Dr. Reddy's to launch a generic memantine hydrochloride product the later of

Dr. Reddy's Settlement Agreement, Exhibit B (License Agreement), at § 1.16, 2.1, 3.2, Litvin Ex. 8.

132. Dr. Reddy's was eligible to begin marketing (per the settlement agreement, without accounting for any required FDA approval) a generic memantine hydrochloride product by July 11, 2015. *Id.*; PSOF44. This was three-months prior to October 11, 2015, the date on which pediatric exclusivity for the '703 patent would have expired. *See Forest Labs., Inc. v. Cobalt Labs., Inc.*, 08-cv-021, D.I. 464 (D. Del.) (the "Dr. Reddy's Order"), at 3-4, Adam Ex. 10.

133. After the execution of a settlement between Forest and Dr. Reddy's, the district court entered a Stipulation and Order, which "finally resolve[d]" the litigation. *See* Dr. Reddy's Order, at 4, Adam Ex. 10.

134. The Dr. Reddy's Order is a final, un-appealable judgment, in which Dr. Reddy's stipulated that its Paragraph IV ANDA filing constituted an act of infringement and it had "not rebutted the statutory presumption that the '703 patent is valid and enforceable." Dr. Reddy's Order, at 2, Adam Ex. 10.

135. The Dr. Reddy's Order further includes a permanent injunction, which reads:

> DRL, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them . . . are hereby enjoined from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, the generic tablet products . . . that are the subject of ANDA No. 90-048 during the life of the '703 Patent, including any extensions and pediatric exclusivities, absent a license agreement or other authorization by Plaintiffs[.]

Dr. Reddy's Order, at 3-4, Adam Ex. 10.

136.

D. Lupin

137. Forest's settlement with Lupin allows Lupin to launch a generic memantine hydrochloride product the later of

Lupin Settlement Agreement, Exhibit B (License Agreement), at § 1.12, 2.1, 3.2, Litvin Ex. 11.

138. Lupin was eligible to begin marketing (per the settlement agreement, without accounting for any required FDA approval) a generic memantine hydrochloride product by July 11, 2015. *Id.*; PSOF58. This was three-months prior to October 11, 2015, the date on which pediatric exclusivity for the '703 patent would have expired. *See Forest Labs., Inc. v. Cobalt Labs., Inc.*, 08-cv-021, D.I. 502 (D. Del.) (the "Lupin Order"), at 4, Adam Ex. 12.

139. After the execution of a settlement between Forest and Lupin, the district court entered a Stipulation and Order, which "finally resolve[d]" the litigation. *See* Lupin Order, at 5, Adam Ex. 12.

140. The Lupin Order is a final, un-appealable judgment, in which Lupin stipulated that its Paragraph IV ANDA filing constituted an act of infringement and it had "not rebutted the statutory presumption that the '703 patent is valid and enforceable." Lupin Order, at 3, Adam Ex. 12.

141. The Lupin Order further includes a permanent injunction, which reads:

> Lupin, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them . . . are hereby enjoined from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, the generic tablet products . . . that are the subject of ANDA No. 90-051 during the life of the '703 patent, including any extensions and pediatric exclusivities, absent a license agreement or other authorization by Plaintiffs[.]

Lupin Order, at 4, Adam Ex. 12.

E. <u>Mylan</u>

142. Forest's settlement with Mylan allows Mylan to launch a generic memantine hydrochloride product the later of

Mylan Settlement Agreement, Exhibit B (License Agreement), at § 1.13, 2.1, 3.2, Litvin Ex. 13.

143. Mylan was eligible to begin marketing (per the settlement agreement, without accounting for any required FDA approval) a generic memantine hydrochloride product by July 11, 2015. *Id.*; PSOF72. This was three-months prior to October 11, 2015, the date on which pediatric exclusivity for the '703 patent would have expired. *See Forest Labs., Inc. v. Lupin Pharms., Inc.*, 08-cv-021, D.I. 500 (D. Del.) (the "Mylan Order"), at 3-4, Adam Ex. 13.

144. After the execution of a settlement between Forest and Mylan, the district court entered a Stipulation and Order, which "finally resolve[d]" the litigation. *See* Mylan Order, at 4, Adam Ex. 13.

145. The Mylan Order is a final, un-appealable judgment, in which Mylan stipulated that its Paragraph IV ANDA filing constituted an act of infringement and it had "not rebutted the statutory presumption that the '703 patent is valid." Mylan Order, at 2, Adam Ex. 13.

146. The Mylan Order further includes a permanent injunction, which reads:

> Mylan, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them . . . are hereby enjoined from offering to sell or selling within the United States the generic tablet products . . . that are the subject of ANDA No. 79-225 during the life of the '703 Patent, including any extensions and pediatric exclusivities, absent a license agreement or other authorization by Plaintiffs[.]

Mylan Order, at 3-4, Adam Ex. 13.

F. <u>Orchid</u>

147. Forest's settlement with Orchid allows Orchid to launch a generic memantine hydrochloride product the later of

Orchid Settlement Agreement, Exhibit B (License Agreement), at § 1.14, 2.1, 3.2, Litvin Ex. 15.

148. Orchid was eligible to begin marketing (per the settlement agreement, without accounting for any required FDA approval) a generic memantine hydrochloride product by July 11, 2015. *Id.* This was three-months prior to October 11, 2015, the date on which pediatric exclusivity for the '703 patent would have expired. *See Forest Labs., Inc. v. Orgenus Pharma Inc.*, 09-cv-5105, D.I. 26 (D.N.J.) (the "Orchid Order"), at 3-4, Adam Ex. 13.

149. After the execution of a settlement between Forest and Orchid, the district court entered a Stipulation and Order, which "finally resolve[d]" the litigation. *See* Orchid Order, at 5, Adam Ex. 14.

150. The Orchid Order further includes a permanent injunction, which reads:

> Orchid, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them . . . are hereby enjoined from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, the generic table products . . . that are the subject of ANDA No. 90-044 during the life of the '703 patent, including any extensions and pediatric exclusivities, absent a license agreement or other authorization by Plaintiffs[.]

Orchid Order, at 4, Adam Ex. 14.

G. <u>Sun</u>

151. Forest's settlement with Sun allows Sun to launch a generic memantine hydrochloride product the later of

Sun Settlement Agreement, Exhibit B (License Agreement), at § 1.12, 2.1, 3.2, Litvin Ex. 16.

152. Sun was eligible to begin marketing (per the settlement agreement, without accounting for any required FDA approval) a generic memantine hydrochloride product by July 11, 2015. *Id.*; PSOF99. This was three-months prior to October 11, 2015, the date on which

pediatric exclusivity for the '703 patent would have expired. *See Forest Labs., Inc. v. Cobalt Labs., Inc.*, 08-cv-021, D.I. 434 (D. Del.) (the "Sun Order"), at 3-4, Adam Ex. 15.

153. After the execution of a settlement between Forest and Sun, the district court entered a Stipulation and Order, which "finally resolve[d]" the litigation. *See* Sun Order, at 4, Adam Ex. 15.

154. The Sun Order is a final, un-appealable judgment, in which Sun stipulated that its Paragraph IV ANDA filing constituted an act of infringement and it had "not rebutted the statutory presumption that the '703 patent is valid and enforceable." Sun Order, at 2, Adam Ex. 15.

155. The Sun Order further includes a permanent injunction, which reads:

> Sun, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them . . . are hereby enjoined from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, the generic tablet products . . . that are the subject of ANDA No. 90-058 during the life of the '703 Patent, including any extensions and pediatric exclusivities, absent a license agreement or other authorization by Plaintiffs[.]

Sun Order, at 3-4, Adam Ex. 15.

H. Teva

156. Forest's settlement with Teva allows Teva to launch a generic memantine hydrochloride product

Teva Settlement Agreement, Exhibit B (License Agreement), at § 1.14, 2.1, 3.2, Litvin Ex. 17.

157. Teva was eligible to begin marketing (per the settlement agreement, without accounting for any required FDA approval) a generic memantine hydrochloride product by July 11, 2015. *Id.* This was three-months prior to October 11, 2015, the date on which pediatric exclusivity for the '703 patent would have expired. *See Forest Labs., Inc. v. Cobalt Labs., Inc.*, 08-cv-021, D.I. 452 (D. Del.) (the "Teva Order"), at 3-4, Adam Ex. 13.

158. After the execution of a settlement between Forest and Teva, the district court entered a Stipulation and Order, which "finally resolve[d]" the litigation. *See* Teva Order, at 4, Adam Ex. 16.

159. The Teva Order further includes a permanent injunction, which reads:

> Teva, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them . . . are hereby enjoined from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, the generic tablet products . . . that are the subject of ANDA No. 90-052 during the life of the '703 Patent, including any extensions and pediatric exclusivities, absent a license agreement or other authorization by Plaintiffs[.]

Teva Order, at 3, Adam Ex. 16.

I. Upsher-Smith

160. Forest's settlement with Upsher-Smith allows Upsher-Smith to launch a generic memantine hydrochloride product the later of

Upsher-Smith Settlement Agreement, Exhibit B (License Agreement), at § 1.13, 2.1, 3.2, Adam Ex. 17.

161. Upsher-Smith was eligible to begin marketing (per the settlement agreement, without accounting for any required FDA approval) a generic memantine hydrochloride product by July 11, 2015. *Id.* This was three-months prior to October 11, 2015, the date on which

pediatric exclusivity for the '703 patent would have expired. *See Forest Labs., Inc. v. Cobalt Labs., Inc.*, 08-cv-021, D.I. 416 (D. Del.) (the "Upsher-Smith Order"), at 3-4, Adam Ex. 18.

162. After the execution of a settlement between Forest and Upsher-Smith, the district court entered a Stipulation and Order, which "finally resolve[d]" the litigation. *See* Upsher-Smith Order, at 4, Adam Ex. 18.

163. The Upsher-Smith Order is a final, un-appealable judgment, in which Upsher-Smith stipulated that its Paragraph IV ANDA filing constituted an act of infringement and it had "not rebutted the statutory presumption that the '703 patent is valid and enforceable." Upsher-Smith Order, at 2, Adam Ex. 18.

164. The Upsher-Smith Order further includes a permanent injunction, which reads:

> Upsher-Smith, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them . . . are hereby enjoined from offering to sell or selling within the United States the generic tablet products . . . that are the subject of ANDA No. 90-043 during the life of the '703 patent, including any extensions and pediatric exclusivities, absent a license agreement or other authorization by Plaintiffs[.]

Upsher-Smith Order, at 3-4, Adam Ex. 18.

165.

166. On July 31, 2015, the FDA sent Upsher-Smith a letter notifying them of their ANDA's approval. *See* Letter from William P. Rickman (FDA, Acting Deputy Director, Office of Generic Drugs) to Upsher-Smith (Attn: Hannah Ochola, Principal Regulatory Affairs CMC Specialist) (July 31, 2015), Adam Ex. 20. In this letter, the FDA noted the following:

> The RLD upon which you have based your ANDA, Namenda Tablets, 5 mg and 10 mg, of Forest Laboratories, LLC (Forest), is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 5,061,703 (the '703 patent), is scheduled to expire on October 11, 2015 (with pediatric exclusivity). You have provided a copy of a letter from Forest Laboratories, LLC that waives the pediatric exclusivity period associated with the '703 patent and permits you to retain protected language covered by the pediatric exclusivity. The waiver is effective from July 1, 2015. This ANDA is, therefore, eligible for approval.

Id.

J. Wockhardt

167. Forest's settlement with Wockhardt allows Wockhardt to launch a generic memantine hydrochloride product the later of

Wockhardt Settlement Agreement, Exhibit B (License Agreement), at § 1.12, 2.1, 3.2, Adam Ex. 21.

168. Wockhardt was eligible to begin marketing (per the settlement agreement, without accounting for any required FDA approval) a generic memantine hydrochloride product by July 11, 2015. *Id.* This was three-months prior to October 11, 2015, the date on which pediatric

exclusivity for the '703 patent would have expired. *See Forest Labs., Inc. v. Cobalt Labs., Inc.*, 08-cv-021, D.I. 419 (D. Del.) (the "Wockhardt Order"), at 3-4, Adam Ex. 22.

169. After the execution of a settlement between Forest and Wockhardt, the district court entered a Stipulation and Order, which "finally resolve[d]" the litigation. *See* Wockhardt Order, at 4, Adam Ex. 22.

170. The Wockhardt Order further includes a permanent injunction, which reads:

> Wockhardt, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them . . . are hereby enjoined from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, the generic tablet products . . . that are the subject of ANDA No. 90-073 during the life of the '703 patent, including any extensions and pediatric exclusivities, absent a license agreement or other authorization by Plaintiffs[.]

Wockhardt Order, at 3-4, Adam Ex. 22.

171.

172. On September 4, 2015, the FDA sent Wockhardt a letter notifying them of their ANDA's approval. *See* Letter from William P. Rickman (FDA, Acting Deputy Director, Office of Generic Drugs) to Wockhardt USA LLC (Attn: Leanna Usa, Manager Regulatory Affairs) (Sept. 4, 2015), Adam Ex. 24. In this letter, the FDA noted the following:

> The RLD upon which you have based your ANDA, Namenda Tablets, 5 mg and 10 mg, of Forest is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 5,061,703 (the '703 patent), is scheduled to expire on October 11, 2015 (with pediatric exclusivity). You have provided a copy of a letter from Forest that waives the pediatric exclusivity period associated with the '703 patent and permits you to retain protected language covered by the pediatric exclusivity. The waiver is effective from July 1, 2015. This ANDA is, therefore, eligible for approval.

Id.

K. Torrent

173. Torrent Pharmaceuticals Limited ("Torrent") submitted a paragraph IV certification along with ANDA No. 200-155 that argued "the claims of the '703 patent are invalid and/or will not be infringed by Torrent's Memantine Hydrochloride 5 mg and 10 mg oral tablets." *See* Torrent's Paragraph IV Certification, Adam Ex. 27. On October 26, 2009, Torrent sent a letter to Forest detailing this paragraph IV certification. *See id.*

174. Forest settled with Torrent on December 7, 2009, without filing a lawsuit regarding Torrent's infringement. *See* Torrent Settlement Agreement, Adam Ex. 28. Forest's settlement with Torrent allows Torrent to launch a generic memantine hydrochloride product on the later of

Id., Exhibit B (License Agreement), at § 1.11, 2.1, 3.2.

175. Torrent therefore was eligible to begin marketing a generic memantine hydrochloride product by October 11, 2015, upon the expiry of Forest's pediatric exclusivity. *See id.*

176. The FDA approved the Torrent generic memantine hydrochloride product on October 13, 2015; the first business day after the expiry of Forest's pediatric exclusivity. *See* FDA, *Memantine Hydrochloride*, Drugs@FDA, Adam Ex. 29.

Dated: March 16, 2017

Respectfully submitted,

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EXHIBIT 77

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

THE PEOPLE OF THE STATE OF NEW YORK, by and through ERIC T. SCHNEIDERMAN, Attorney General, Plaintiff, v. ACTAVIS plc and FOREST LABORATORIES, LLC, Defendants.	No.: 14-cv-7473 **FILED UNDER SEAL**

DECLARATION OF WILLIAM J. MEURY

I, William J. Meury, declare as follows:

1. I am Executive Vice President, North American Brands at Actavis plc. Prior to Actavis' July 1, 2014, acquisition of Forest Laboratories, Inc., I was Executive Vice President, Sales and Marketing for Forest Laboratories, Inc. ("Forest").

2. I respectfully submit this Declaration in support of Forest's Request to Stay the Preliminary Injunction.

3. While we do not yet know the terms and scope of the preliminary injunction the Court intends to enter, to the extent that the injunction forces Forest to take affirmative steps to manufacture and sell Namenda IR when it would otherwise discontinue general distribution of the product, and requires Forest to divert its resources from the manufacture and production of new pharmaceutical products so that it can sell an older drug, at unspecified volumes through unspecified channels for an unspecified duration, Forest will be irreparably harmed.

4. As set forth more fully below, an injunction that prevents Forest from discontinuing general distribution of Namenda IR will cause irreparable harm to Forest [redacted]

I. FACTUAL BACKGROUND

a. Forest's Investment in Namenda

5. In June 2000, Forest obtained an exclusive license to U.S. Patent No. 5,061,703 held by Merz Pharma GmbH & Co. KGaA. In December 2002, Forest submitted a New Drug Application ("NDA") to the FDA, seeking approval to market memantine HCL tablets (5mg and 10mg) branded as "Namenda" for the treatment of Alzheimer's.

6. Since 2000, Forest has expended approximately [redacted] researching and developing Namenda, the last molecular entity approved by the FDA to treat Alzheimer's disease. Of that [redacted], Forest has invested roughly [redacted] in clinical trials and other research and development and expended an additional [redacted] in royalty payments to Merz to compensate Merz for its memantine discovery and the sale of Namenda in the United States.

7. Forest initially introduced twice-daily Namenda IR tablets to the market in 2004. At that time, Namenda was the first and only medication approved for the treatment of moderate to severe Alzheimer's disease. In 2005, Forest introduced a twice-daily liquid version of Namenda IR (often referred to as "oral solution") for patients who have difficulty swallowing tablets, although any Namenda patient may take it.

8. Forest also has invested substantial resources in exploring other potential treatment uses for Namenda, including for pediatric autism, depression, and neuropathic pain, which, like Alzheimer's disease, currently have no cure. In addition, Forest invested almost $70 million in support of clinical trials for the treatment of pediatric autism.

9. Twelve generic manufacturers have obtained and currently maintain tentative approval from the FDA to market their generic versions of Namenda IR tablets. [redacted] generic competitors may begin selling their generic versions of Namenda IR tablets as early as July 11, 2015. [redacted] more are expected to launch their generic versions as early as October 11, 2015.

b. Namenda XR

10. After launching Namenda IR, Forest continued extensive development efforts, including investing approximately [redacted] in research and development for a once-daily, extended release version of Namenda called Namenda XR. Forest also invested over [redacted] in creating and training a salesforce to educate physicians, caregivers and pharmacists about Namenda XR. In June 2013, Forest launched Namenda XR.

11. There are many advantages of Namenda XR over Forest's other versions of Namenda. Among other things, (1) Namenda XR is approved for once-daily dosing, whereas Namenda IR must be taken twice-daily; (2) unlike Namenda IR, Namenda XR is approved for applesauce dosing, which means the FDA has confirmed it may be sprinkled over applesauce to

ease swallowing; (3) unlike Namenda IR, Namenda XR supports development of a fixed dose combination pill with donepezil, another Alzheimer's Disease treatment; and (4) unlike Namenda IR, Namenda XR has been tested in combination with all three acetylcholinesterase inhibitors also used to treat Alzheimer's disease, a benefit to physicians, payors, patients and caregivers.

12. Moreover, Namenda XR reduces the pill burden on an Alzheimer's patient by 365 doses per year, as compared to Namenda IR. It also reduces the burden on caregivers and helps limit dispensing errors, which are a well-known problem in the health care area. Furthermore, the fixed-dose combination of Namenda XR and donepezil has the potential to reduce the burden on an Alzheimer's patient even further to a single pill per day.

13. Since the launch of Namenda XR in June 2013, doctors and patients have shown strong acceptance of Namenda XR and have readily switched many patients to Namenda XR.

14. Forest has been successful in getting Namenda XR on formularies of health plans in a preferred position, which has facilitated conversion of patients from Namenda IR to Namenda XR. Pursuant to industry practice, Forest is offering rebates on both Namenda XR and Namenda IR if Medicare Part D Plan Sponsors put the products on a preferred formulary tier. [redacted].

15. Forest has discounted Namenda XR relative to Namenda IR. The average selling price of Namenda XR is [redacted] the average selling price of Namenda IR. Total discounts given by Forest for Namenda XR exceed [redacted].

c. The Decision to Discontinue Namenda IR Tablets

16. After the launch of Namenda XR, Forest began evaluating whether to discontinue Namenda IR tablets. Armed with a new, improved product that offered patients and caregivers a

[redacted]

17. Giving Namenda XR an opportunity to compete with generic IR tablets would result in other benefits. First, it would allow Forest to attempt to recoup its significant investment in the better drug, Namenda XR. Second, it would permit Forest to focus its resources—marketing, distribution, regulatory and otherwise—on Namenda XR and the fixed-dose combination product discussed above. And because Namenda XR is a better product with the same active ingredient as Namenda IR, Forest had no reason to continue to put resources behind the older product.

18. Slowing Namenda XR's decline would also allow Forest to save jobs that might otherwise be lost as a result of the "patent cliff."

19. Maintaining older products not only means Forest has to keep up with regulatory filings and requests, but also manage supply chain issues, including maintaining inventory and handling returns. All of these costs and burdens distract focus away from the development of new treatments.

20. Carrying both Namenda XR and Namenda IR also creates an administrative burden and increases inventory carrying costs for Forest's customers, i.e., wholesalers and retail pharmacies.

21. In deciding whether to discontinue Namenda IR tablets, Forest commissioned multiple surveys conducted by third-party health care market research firms over a period of three months in the Fall 2013, at a cost of more than [redacted]. Overall, more than 950 physicians, caregivers and pharmacists were surveyed. By large margins, physicians and

caregivers expressed strong satisfaction with Namenda XR and agreed that it would be acceptable if Namenda IR were no longer available.

22. The Namenda XR surveys reaffirmed what Forest concluded internally, i.e., that Namenda XR is preferred over Namenda IR, and that caregivers, physicians and pharmacists do not believe that Forest needs to offer Namenda IR if Namenda XR is available.

23. On February 7, 2014, Forest first notified the FDA of its plan to discontinue Namenda IR tablets but to continue marketing the oral solution. On February 14, 2014, Forest publicly announced its plan to focus its manufacturing and marketing efforts on once-daily Namenda XR and discontinue the sale of Namenda IR tablets effective August 15, 2014. On June 10, 2014, due to manufacturing issues with Namenda XR, Forest issued another press release saying that the discontinuation of Namenda IR would be delayed until the fall of 2014.

24. In connection with the transition to Namenda XR, Forest has not withdrawn any inventory of Namenda IR tablets. Nor has Forest destroyed its own Namenda IR inventory or withdrawn its NDA for Namenda IR.

25. Absent an injunction, Forest planned to allow Namenda IR tablets in the current distribution channels to be exhausted in the normal course. Further, Forest planned to provide for the continued distribution of Namenda IR tablets through a specialty pharmacy distribution system. Forest has contracted with Foundation Care, a full service retail pharmacy with specialty services and coverage in all 50 states and the District of Columbia, to provide Namenda IR to any patients with specific medical needs.

d. The Injunction

26. On September 24, 2014, the New York Attorney General Antitrust Bureau filed a Motion for a Preliminary Injunction against Forest, seeking to enjoin Forest from discontinuing

or otherwise restricting the sale of Namenda IR. Judge Robert Sweet of the United States District Court for the Southern District of New York held a hearing on the Bureau's motion from November 10, 2014 through November 14, 2014. On December 11, 2014, the Court issued an opinion and order stating that a preliminary injunction will issue, without yet specifying the scope of the injunction or the date it will issue, pending a hearing scheduled for December 15, 2014.

II. THE INJUNCTION WOULD CAUSE FOREST IRREPARABLE HARM

27. To the extent the injunction forces Forest to abandon its current business strategy and manufacture and sell Namenda IR in general distribution, it will cause Forest and the general public [redacted] harm that cannot be rectified should Forest prevail on appeal.

a. Irreparable Harm Would Be Immediate

28. [redacted]

29. [redacted]

30. [redacted]

b. Irreparable Harm to the Market for Namenda XR

31. [redacted]

32. [redacted]

33. [redacted]

[redacted]

34. More broadly, based on Forest's public announcements and course of dealing with its customers (including all major health plans and other managed care entities), there is an established expectation throughout the health care industry that Namenda XR will be distributed on a wide basis in the immediate future and that Namenda IR will be distributed through a specialty distribution channel (Foundation Care). Given that generally-accepted expectation relating to the relative production and distribution of Namenda XR as compared with Namenda IR, I believe that any court-imposed requirement that forces Forest to alter its business strategies and fully manufacture and distribute Namenda IR would cause serious uncertainty in the marketplace and could have unintended and unpredictable results.

b. Irreparable Harm to the Development of Alzheimer's Treatments

35. Because Forest is the last brand-name pharmaceutical company still actively promoting in the Alzheimer's Disease space and engaged in continuing research and development into Alzheimer's treatments, an injunction forcing Forest to manufacture and distribute Namenda IR in general distribution would have a detrimental impact on the public at large, who would be deprived of innovative and life-changing products in the Alzheimer's field.

36. [redacted]

c. Irreparable Harm to Forest's Overall Research and Development Efforts

37. As noted, if an injunction forcing Forest to continue to manufacture and sell Namenda IR in general distribution is not stayed (and remains in force), Forest would be forced to curtail its extensive research and development efforts aimed at creating new and innovative drugs.

38. [redacted]

39. [redacted]

[redacted]

40. [redacted]

d. Irreparable Injury to Forest's Employees

41. [redacted]

42. [redacted]

e. Irreparable Injury to Forest's Public Assistance Programs

43. [redacted]

I certify under penalty of perjury that the foregoing is true and correct. Executed on December 12, 2014.

William J. Meury